Petition

81-950

No.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

JAMIESON-MCKAMES PHARMACEUTICALS, INC.,
PHARMACARE GENERIC DRUGS, INC.,
PHARMACARE, INC.,
PAYLESS PHARMACY, INC.,
JAMES C. JAMIESON, SR., and
JAMES C. JAMIESON, JR.,
Petitioners,

vs.

UNITED STATES OF AMERICA,

On Writ of Certiorari
To the United States Court of Appeals
for the Eighth Circuit

PETITION FOR WRIT OF CERTIORARI

IRL B. BARIS
611 Olive Street - Suite 2020
St. Louis, Missouri 63101
(314) 231-1312
(Counsel of record)

MARC L. SANDBERG
1015 Locust Street - Suite 1140
St. Louis, Missouri 63101
(314) 231-1884
Attorneys for Petitioners

St. Louis Law Printing Co., Inc., 411 No. Tenth Street 63101 314-231-4477

QUESTIONS PRESENTED FOR REVIEW

I.

Whether searches and seizures by FDA agents in a criminal investigation, acting under 21 U.S.C. § 374 without a warrant or with a warrant admittedly not based upon traditional probable cause standards, violated the Fourth Amendment to the Constitution of the United States, including the following questions:

A. Whether the drug-manufacturing industry is a pervasively regulated industry and therefore an exception to the rule of *Marshall* v. *Barlow's, Inc.,* 436 U.S. 307 (1978), which invalidates warrantless searches of business premises.

B. If the drug-manufacturing industry is a pervasively regulated industry, whether Fourth Amendment probable cause standards are required for searches in a criminal investigation.

II.

Whether, for purposes of criminal and civil forfeiture proceedings, the definition of a "counterfeit drug" contained in 21 U.S.C. § 321(g)(2) applies to the marketing of "look-alike" generic drugs, having similarities of appearance in size, shape and color to brand name drugs, an issue related to questions presented in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.,* No. 80-2182, and *Darby Drug Co., Inc.* v. *Ives Laboratories, Inc.,* No. 81-11, certiorari granted October 13, 1981.

LIST OF PARTIES

Corporate petitioners are the following:

Jamieson-McKames Pharmaceuticals, Inc.

Pharmacare Generic Drugs, Inc.

Pharmacare, Inc.

Payless Pharmacy, Inc.

Individual petitioners are:

James C. Jamieson, Sr.

James C. Jamieson, Jr.

The corporate petitioners are Missouri corporations, none being publicly owned.

Throughout all of these proceedings, Mr. Robert W. Saitz, a member of the Bar of this Court, was co-counsel for petitioners. Mr. Saitz has just been appointed by the Governor of Missouri to serve as a Circuit Judge of the 21st Judicial Circuit of the State of Missouri, and will therefore not appear as counsel on this petition.

TABLE OF CONTENTS

Page

Questions presented for review i

List of parties ii

Table of contents iii

Table of authorities iv

Opinions below 1

Jurisdiction 2

Constitutional provisions and statutes involved 3

Statement of the case 3

Argument 9

- I. Searches and seizures 9
- II. Look-alike drugs 19

Conclusion 27

Appendix

- A. Opinion of Court of Appeals, dated May 21, 1981 . . . . A-1
- B. Order on rehearing of Court of Appeals, dated August 7, 1981 . . . . A-38
- C. Order of District Court overruling joint motion of defendants to suppress evidence, dated September 7, 1977, including report and recommendation of United States Magistrate, dated September 6, 1977 . . . . A-41

D. Memorandum decision of United States District Court, Eastern District of Missouri, Eastern Division, Hon. John F. Nangle, District Judge, dated March 29, 1979 (criminal case) A-53

E. Order and memorandum of United States District Court, Eastern District of Missouri, Eastern Division, Hon. John F. Nangle, District Judge, dated July 23, 1979 (civil case) A-64

F. Judgment of Court of Appeals, dated May 21, 1981 .... A-71

G. Kendall application for inspection warrant, dated October 23, 1975 .... A-72

H. Warrant for inspection issued by Magistrate Bahn on October 23, 1975 .... A-75

I. Notice of inspection for Morganford premises, dated October 29, 1975 .... A-77

J. Notice of inspection for Wentzville premises, dated October 29, 1975 .... A-82

K. Constitutional provisions involved A-84

L. Statutes involved A-85

TABLE OF AUTHORITIES

Cases

Aguilar v. Texas, 378 U.S. 108 (1964) 15

Andresen v. Maryland, 427 U.S. 463 (1976) 16

Camara v. Municipal Court, 387 U.S. 523 (1967) 18

Colonnade Catering Corp. v. United States, 397 U.S. 72 (1970) . . . 12,13,18

Darby Drug Co., Inc. v. Ives Laboratories, Inc., No. 81-11, cert. gr. Oct. 13, 1981 . . . i,20

Delaware v. Prouse, 440 U.S. 648 (1979) . . . 18

Donovan v. Dewey, ____ U.S. ____, 69 L.Ed. 2d 262 (1981) . . . 13,14,15,17,18

G. M. Leasing Corp. v. United States, 429 U.S. 338 (1977) . . . 18

Inwood Laboratories, Inc. v. Ives Laboratories, Inc., No. 80-2182, cert. gr. Oct. 13, 1981 . . . i,20

Ives Laboratories, Inc. v. Darby Drug Co., 638 F. 2d 538 (2nd Cir. 1981) . . . 21,27

Lo-Ji Sales, Inc. v. New York, 442 U.S. 319 (1979) . . . 16

Marron v. United States, 275 U.S. 192 (1927) . . . 16

Marshall v. Barlow's, Inc., 436 U.S. 307 (1978) . . . i,7,12,14,15, 16,18

Marshall v. Horn Seed Co., Inc. 647 F. 2d 96 (10th Cir. 1981) . . . 17

Michigan v. Tyler, 436 U.S. 499 (1978) . . . 17,18

Nathanson v. United States, 290 U.S. 41 (1933) . . . 15

See v. Seattle, 387 U.S. 541 (1967) . . . 18

Spinelli v. United States, 393 U.S. 410 (1969) . . . 15

Stanford v. Texas, 379 U.S. 476 (1965) . . . 16

Steagald v. United States, ____ U.S. ____, 68 L.Ed. 2d 38 (1981) . . . 18

United States v. All Equipment Including, But Not Limited To, An Encapsulating Machine Not Identified As To Manufacturer, 475 F. Supp. 39 (E.D. Mo. 1979) 2,7

United States v. Biswell, 406 U.S. 311 (1972) 12,13,18

United States v. Device Labeled Theramatic, 641 F. 2d 1289 (9th Cir. 1981) 17

United States v. Jamieson-McKames Pharmaceuticals, Inc., 651 F. 2d 532 (8th Cir. 1981) 1

United States v. Lawson, 502 F. Supp. 158 (D. Md. 1980) 17

United States v. Pappas, 613 F. 2d 324 (1st Cir. 1979) .. 17

United States v. Piner, 608 F. 2d 358 (9th Cir. 1979) 16

United States v. Raub, 637 F. 2d 1205 (9th Cir. 1980) ... 15

United States v. Shaefer, Michael and Clairton Slag, Inc., 637 F. 2d 200 (3rd Cir. 1980) 15,17

Constitutional provisions

Fourth Amendment, Constitution of the United States . 3,9,11 12,15,16,17,18,19

Statutes

Title 21, United States Code:

§ 321 .... i,3,21,25,26

§ 331 3,4

§ 333 3,4

§ 334 3,4,7,17

§ 351 3
§ 352 3
§ 374..i,3,11,12,14

Miscellaneous

Congressional Record, 4421 (March 9, 1965) 22
Drug Abuse Control Amendment of 1965, P.L. 89-74 .. 21
Senate Report No. 337 (89th Cong.) at 8.............. 22
49 U.S. Law Week 3875 17

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James C. Jamieson, Sr., and
James C. Jamieson, Jr.,
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PETITION FOR WRIT OF CERTIORARI

OPINIONS BELOW

This cause was decided by a panel of the United States Court of Appeals for the Eighth Circuit on May 21, 1981, in an opinion which has been reported in *United States* v. *Jamieson-McKames Pharmaceuticals, Inc.,* 651 F. 2d 532 (8th Cir. 1981). The opinion is reproduced as Appendix A hereto.

On August 7, 1981, the Court of Appeals entered an order on rehearing denying petitioners' petition for rehearing or rehearing en banc, denying the government's petition for rehearing, and granting the government's petition for clarification. (See

Appendix B.) This order on rehearing has not yet been officially reported and is not reflected in the opinion at 651 F. 2d 532.

A motion to suppress evidence had been filed by petitioners and was referred by the District Court to the Honorable David D. Noce, who filed his report and recommendation on September 6, 1977. On September 7, 1977, the District Court (Hon. John F. Nangle) entered an order overruling the joint motion of defendants to suppress evidence. This order and the report and recommendation of the Magistrate have not been officially reported; they are reproduced as Appendix C hereto.

After a joint trial of the criminal and civil proceedings, the District Court on March 29, 1979, filed a memorandum, which has not been officially reported, finding all defendants in the criminal case guilty. (See Appendix D.) Thereafter, the District Court on July 23, 1979, entered its order, memorandum and findings in the civil forfeiture proceedings (Appendix E), which is reported in *United States* v. *All Equipment Including, But Not Limited To, An Encapsulating Machine Not Identified As To Manufacturer,* 475 F. Supp. 39 (E.D. Mo. 1979).

JURISDICTION

The judgment of the United States Court of Appeals was entered on May 21, 1981. (See Appendix A and F.) Petitioners filed a timely petition for rehearing and suggestion of appropriateness of rehearing en banc. The government filed a timely petition for clarification or rehearing. All petitions for rehearing were denied on August 7, 1981, and the petition of the government for clarification was granted on said date. (See Appendix B.)

On September 25, 1981, this Court (Justice Blackmun) issued an order extending the time for filing a petition for writ of certiorari to and including November 5, 1981, and on November 3, 1981, a further order extending said time to and including November 19, 1981. (See No. A-256.)

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

This petition involves an interpretation of the Fourth Amendment to the Constitution of the United States, the text of which is set out in Appendix K.

Also involved are various statutory provisions of Title 21, United States Code, the Federal Food, Drug, and Cosmetic Act, particularly sections 321, 331, 333, 334, 351, 352 and 374. Because these statutory provisions are lengthy, their pertinent text is set forth in Appendix L.

STATEMENT OF THE CASE

On October 29, 1975, law enforcement officers of the State of Missouri and the federal government, including State Highway patrolmen, federal marshals and agents of the Food and Drug Administration, entered into and searched the premises of petitioners Jamieson-McKames Pharmaceuticals, Inc. and Pharmacare, Inc., at 3227 Morganford Road, St. Louis, Missouri, and seized numerous items of drugs, equipment, bottles, labels, documents, and other records, without a search warrant based upon probable cause (Mag. Tr. 18-21).[1] At the same time, a similar raid by FDA agents was conducted at a retail pharmacy at Wentzville, Missouri and evidence was seized, also without any search warrant based upon probable cause (Mag. Tr. 34-35).

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[1] The following abbreviations are being used in this petition:

Mag. Tr. - The transcript of proceedings before Magistrate Noce at hearings on motions to suppress evidence in the criminal case (one volume, 131 pages).

On December 19, 1975, a civil complaint for forfeiture of certain items of equipment in the possession of petitioner Jamieson-McKames Pharmaceuticals, Inc. at 3227 Morganford Road was filed by the government in the District Court, pursuant to 21 U.S.C. § 334, alleging that said equipment was used or designed for use in making counterfeit drugs (C.R. 1). Claimant, petitioner Jamieson-McKames Pharmaceuticals, Inc., filed its answer thereto on February 19, 1976, denying that said equipment was used or was designed for use in making counterfeit drugs (C.R. 10).

Thereafter, on May 12, 1977, petitioners Jamieson-McKames Pharmaceuticals, Inc., Pharmacare Generic Drugs, Inc., Pharmacare, Inc., Payless Pharmacy, Inc., Missouri corporations, and James C. Jamieson, Sr. and James C. Jamieson, Jr., as individuals, were charge in an 11-count indictment with counterfeiting, adulterating and misbranding drugs, and conspiracy to counterfeit, adulterate and misbrand drugs, in violation of 21 U.S.C. §§ 331(i)(3), 331(k), and 333(b), and 18 U.S.C. §§ 2 and 371 (Cr.R. 1). All petitioners pleaded not guilty, and on June 10, 1977, filed pre-trial motions, including a motion to suppress the evidence seized by the government in its raids of October, 1975 (Cr.R. 35). The District Court, on July 11, 1977, referred the motion to suppress evidence to Magistrate David D. Noce (Cr.R. 81), who conducted hearings on August 4, August 26, and August 29, 1977. On September 6, Judge Noce submitted his report to the District Court, recommending

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Tr. - the transcript of proceedings in the consolidated trial before District Judge Nangle (ten volumes, 2514 pages).

Cr.R. - the Record filed in the criminal appeal (Court of Appeals No. 79-1367).

C.R. - the Record filed in the civil appeal (Court of Appeals No. 79-1708).

GX - Government Exhibits introduced at the trial.

DX - Defendants Exhibits introduced at the trial.

that the motion to suppress be overruled (Cr.R. 249). On September 7, the District Court adopted the Magistrate's report and recommendation (Cr.R. 260). A copy of the District Court Order and the Magistrate's report is attached to this petition as Appendix C.

The civil forfeiture matter was consolidated for trial with the criminal cause, with the consent of the parties and the permission of the District Court. A jury being waived, trial of this consolidated cause commenced on September 19, 1977, and after more than 20 days of trial, concluded on January 17, 1978. Both sides presented evidence at the trial. Much of the government's evidence emanated from the searches and seizures at Morganford, Wentzville and a dispensary on Chambers Road — the subject of Question I presented by this petition. The evidence relevant to a consideration of this question is discussed in greater detail in the Argument portion of this petition.

Inasmuch as the sufficiency of the evidence at trial is not directly presented in this certiorari proceeding, petitioners will not lengthen this petition with a detailed recitation of the evidence. Suffice it to say that the government, in an effort to show that there had been violations of the law pertaining to counterfeiting, misbranding or adulterating of drugs, presented evidence concerning generic drug products manufactured and/or distributed by one or more of the petitioners. (This evidence, particularly with reference to "look-alike" drugs, has some relevance to Question II presented by this petition, and, to the extent deemed appropriate, is discussed in the Argument portion of this petition.) Petitioners' evidence related basically to their procedures for the legitimate manufacturing and marketing of generic drug products through wholesale outlets and retail pharmacies.

Following the close of the evidence on January 17, 1978, the parties briefed the issues for the District Court. Almost two years from the date of the indictment, the District Court, on

March 29, 1979 filed its Memorandum (see Appendix D), which included certain findings of fact in the criminal case, and found all petitioners guilty on all eleven counts of the indictment. The trial Court reserved judgment on the civil portion of this matter at that time (Tr. 2497-2499).

On April 20, 1979, the District Court entered its Judgments and Commitments (Cr.R. 533-554) wherein the court sentenced each of the individual petitioners to imprisonment for a term of three years and a fine of $5,000.00 under Count I (conspiracy) and further to a term of one year and a fine of $5,000.00 on nine of the other counts of the indictment. Some of the imprisonment sentences were to run consecutively, while others were to run concurrently. The District Court specifically stated that it was the Court's intention that the sentences of imprisonment total eight years, and that the fines total Fifty Thousand Dollars ($50,000.00) for each individual defendant. The Court suspended imposition of sentence as to Count IV and placed the individuals on probation for a period of five years following the completion of the sentence of imprisonment under the other counts, with the standard conditions and the further condition that they not participate in the manufacture, distribution, and/or sale of prescription drugs and/or controlled substances. The term of imprisonment as to petitioner Jamieson, Sr. only was under the parole provisions of 18 U.S.C. § 4205(b)(2) (Tr. 2508-2511). Each of the four corporate defendants was fined the sum of $2,000.00 on each of the eleven counts, or $22,000.00 apiece, for a total of $88,000.00 (Tr. 2511-2512). On April 30, 1979, all of the defendants in the criminal case duly filed their notices of appeal to the United States Court of Appeals for the Eighth Circuit (Cr.R. 555-556).

On July 23, 1979, the trial Court entered its Order, Memorandum and Findings in the civil portion of this litigation, condemning and forfeiting the equipment herein, denying the claim of petitioner Jamieson-McKames Pharmaceuticals, Inc. to said equipment, and further ordering the United States Marshal to sell the equipment pursuant to the provisions of 21 U.S.C. § 334(b)(1) (C.R. 14). See *United States* v. *All Equipment Including, But Not Limited To, An Encapsulating Machine Not Identified As To Manufacturer*, 475 F. Supp. 39 (E.D. Mo. 1979), reproduced as Appendix E to this petition. Petitioner Jamieson-McKames Pharmaceuticals, Inc. duly filed its notice of appeal to the Court of Appeals (C.R. 22), and the appeals were consolidated for briefing and argument in that Court.

On May 21, 1981, the Court of Appeals issued an opinion generally affirming the judgments of the District Court. Most of the Court's opinion centered on the troublesome issue of the validity of the searches, particularly in the light of *Marshall* v. *Barlow's, Inc.*, 436 U.S. 307 (1978). The opinion upheld the searches as to Morganford and Chambers, but reversed the convictions on Counts VII and VIII and remanded those counts to the District Court for further findings on the issue of consent.[2] The opinion of the Court of Appeals is reproduced as Appendix A to this petition, and is reported at 651 F.2d 532.

Petitioners filed a petition for rehearing, with a suggestion of appropriateness of rehearing en banc. The government filed a petition for rehearing or for clarification of the meaning of the Court of Appeals on the consent question involved in the Wentzville search. On August 7, 1981, the Court of Appeals (see Appendix B) denied the petitions of both sides for rehearing but entered an order attempting to clarify its meaning as to the consent issue. (That portion of this case with reference to Counts VII and VIII has now been remanded to the District Court, which recently indicated that it would hold further proceedings in abeyance until the outcome of these certiorari proceedings.)

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[2] The Court of Appeals held that the evidence as to Counts VII and VIII came form the searches at Wentzville and therefore, subject to a determination of the consent issue, that the convictions based upon such evidence were tainted. In the petition for rehearing filed by petitioners in the Court of Appeals, the Court's attention was directed to at least one other count (Count III) in which the evidence emanated solely from Wentzville, and petitioners also suggested that the illegally obtained evidence from Wentzville tainted the consideration of all other counts, including the conspiracy count. The Court of Appeals did not comment in the original opinion or in the order on rehearing as to the effect on other counts.

This petition for a writ of certiorari seeks to review the judgment of the Court of Appeals affirming the convictions of petitioners on nine of the eleven counts of the indictment and affirming the judgment of the District Court in the civil forfeiture proceedings.

ARGUMENT

I.

Searches and seizures

After several months (Tr. 1023) of consultation, planning and preparation among FDA agents, State agents, and the United States Attorney (Tr. 1136-1137), raids of the premises at 3227 Morganford Road and at a pharmacy in Wentzville were simultaneously executed, starting on October 29, 1975. A plan of action had already been prepared by FDA agent Kendall, and each participant in the raid had specific duties (Tr. 1139-1140). The raids were clearly part of a criminal investigation, and FDA agents testified that the objective of the investigation was a criminal prosecution (Tr. 1024, 1135-1137). The Court of Appeals stated in footnote 19 of its opinion: "The appellants argue that there can be little doubt that the government contemplated bringing criminal charges. The evidence supports this view."

The Morganford raid lasted for five days and resulted in the seizure of thousands of samples, bottles and other evidence — the list was 17 pages long (Cr.R. 137). Documents were examined and photocopied, and hundreds of pictures were taken (Mag. Tr. 122-125). Numerous items of evidence were also seized from the Wentzville pharmacy, where the raid lasted for two days (Mag. Tr. 34-35). A pre-trial motion (Cr. R. 35) to suppress evidence seized at Morganford and Wentzville was heard by Magistrate Noce (Mag. Tr.), who recommended that it be denied (Cr. R. 249), and his recommendation was adopted by the District Court (Cr.R. 260). The Court of Appeals affirmed the seizures as to Morganford and reversed and remanded (on an issue of consent) as to the Wentzville raids.[3]

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[3] Because the consent question has been remanded to the District Court, it is not being presented by this petition. But the validity of searches in a criminal matter, without a search warrant based upon traditional Fourth Amendment probable cause, is a question

A medical dispensary at Chambers Road was also raided, but information about it did not become known until the trial (Tr. 1295); hence there was no pre-trial motion filed to suppress such evidence. The District Court and the Court of Appeals attempted to justify the Chambers search by consent of Dr. Eckert (Cr. R. 529, 651 F. 2d, at 542). Petitioners believe the lower Courts erred because Dr. Eckert had no authority to give consent; that he had no proprietary interest in the Chambers premises or its contents was clear from his testimony that Dr. Salit owned the space and that the contents of the dispensary were owned by Jamieson-McKames (Tr. 1278-1280, 1290, 1296). FDA agent Nesselhauf had no written documentation for the search or seizures at Chambers (Tr. 1640, 1649); he knew that the dispensary was owned and operated by Jamieson-McKames Pharmaceuticals, Inc. Nesselhauf was well aware that the doctors were not the owners of the pharmacy, because he left a receipt made out to petitioner Jamieson, Jr. (Tr. 1650, 1656-1657, DX-VV). Significantly, he admitted that he was instructed by his supervisor not to serve the receipt for seized drugs on Jamieson, Jr., and he was specifically told not to contact Jamieson, Jr. (Tr. 1656). There was a deliberate effort to avoid even seeking consent from the only party known by the agents to be in position to give consent.

In December, 1975, based upon information obtained in the raids, the government filed a complaint for forfeiture and warrant for arrest of property (C. R. 1). This complaint and warrant for arrest was the subject of the civil forfeiture proceedings in this case.

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presented by this petition and affects all searches and seizures in this case, including Wentzville. A ruling in favor of petitioners on this search and seizure question would render the consent issue moot. The District Court has decided to hold further proceedings on the consent issue in abeyance pending a determination of this petition for certiorari.

Petitioners believe that all of the raids were improperly conducted, without legal authorization, that the evidence seized on such raids was obtained in violation of Fourth Amendment requirements, and that all of the evidence should have been suppressed at trial, and the equipment should have been ordered returned to claimant Jamieson-McKames Pharmaceuticals, Inc.[4]

At the outset of the hearing before Magistrate Noce on the motion to suppress, the government indicated that the basis of authority for all the searches was "the Act", presumably 21 U.S.C. § 374 (Mag. Tr. 14). With reference to both Morganford and Wentzville, the government apparently relied on notices of inspection (Exhibits A and C to the government's third supplemental submission) (Mag. Tr. 12-13, Cr. R. 178).

The government's position has not been clear, however, because in earlier pleadings in the motion to suppress stage of these proceedings, they made reference to a warrant for inspection issued by Magistrate Bahn on October 23, 1975, a copy of which was attached as Exhibit A to their supplemental submission on August 4, 1977 (Cr. R. 82). See also Exhibit A to government's second supplemental submission, filed on August 12, 1977 (Cr. R. 137). The application for this inspection warrant was made by FDA agent Kendall on October 23, 1975.[5]

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[4] The premises at Wentzville and Chambers and a part of the Morganford premises were retail pharmacies dispensing prescription drugs in the regular course of their business. As to Morganford, FDA agent Ele acknowledged that the premises gave all of the appearance of a retail pharmacy (Mag. Tr. 113-114). Even if a drug manufacturing establishment may be inspected without a search warrant, the searches and seizures at these retail establishments were expressly prohibited by the exceptions of 21 U.S.C. § 374 (a)(1) and (2). The Court of Appeals erroneously rejected this argument (652 F. 2d, fn. 21), without any evidence of relationship to any manufacturing activities.

[5] For this Court's convenience, we are attaching copies of these documents as an Appendix to this petition:

Appendix G - Kendall application for inspection warrant, dated October 23, 1975.

The Court of Appeals did not accept the government's entire argument, but instead analyzed the case in the light of *Marshall* v. *Barlow's, Inc.*, 436 U.S. 307 (1978). It held first that *Barlow's* generally does not permit warrantless searches, except for industries "long subject to close supervision and inspection," citing *Colonnade Catering Corp.* v. *United States*, 397 U.S. 72 (1970), and "pervasively regulated business[es]," such as in *United States* v. *Biswell*, 406 U.S. 311 (1972). It then held that the drug-manufacturing industry is so closely regulated as to fall within the *Colonnade-Biswell* exception to the warrant requirement. Therefore, the Court held that an inspection pursuant to notice under 21 U.S.C. § 374 is proper where there is valid consent.[6]

The Court of Appeals then discussed the Magistrate's warrant (see Appendix H) with reference to the Morganford search. The Court ruled that *Barlow's* does not require probable cause in the criminal law sense, and that Fourth Amendment search requirements are not applicable in a criminal investigation of a closely regulated business.

Petitioners believe that the Court of Appeals erred in holding that (A) the drug-manufacturing industry is subject to the *Colonnade-Biswell* exception to the warrant requirement enunciated by this Court in *Barlow's*, and (B) Fourth Amendment probable cause requirements are not applicable in a criminal in-

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Appendix H -	Warrant for inspection issued by Magistrate Bahn on October 23, 1975.
Appendix I -	Notice of inspection for Morganford, dated October 29, 1975.
Appendix J -	Notice of inspection for Wentzville, dated October 29, 1975.

[6] As previously indicated, the cause was remanded to the District Court for a determination of the consent issue as to the Wentzville search.

vestigation. We respectfully submit that certiorari should be granted to review the decision of the Court of Appeals because it involves important questions of federal law which have not been, but should be, settled by this Court, and also because the decision below is in conflict with applicable decisions of this Court and other Courts of Appeals.

A. Is the drug-manufacturing industry a closely regulated one?

Petitioners acknowledge the validity of the *Colonnade-Biswell* exceptions for closely or pervasively regulated businesses. Liquor (*Colonnade*) and firearms (*Biswell*) are such industries because of their close connections with illegal activities; regulation is certainly required. The same reasoning, however, does not apply to the drug-manufacturing industry, which is a lawful industry. Even though the drug industry may have been subject to governmental regulation for a number of years, the same can be said of any legitimate industry. All businesses now are to a large extent regulated by the government, and they have been for many years, whether the regulations relate to employment practices, tax reporting, safety regulation, etc.

On June 17, 1981, this Court decided *Donovan* v. *Dewey*, ____ U.S. ____, 69 L.Ed. 2d 262 (1981), and established guidelines for extension of the *Colonnade-Biswell* exception to the mining industry. The Court of Appeals herein did not have the benefit of this Court's opinion in *Donovan* v. *Dewey* when it decided this case on May 21, 1981.[7] We believe that the standards considered by this Court for applying the exception to the warrant requirement must lead to the conclusion that the Court of Appeals erred.

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[7] The Court of Appeals was aware of *Donovan* v. *Dewey* at the time of its order on rehearing dated August 7, 1981, and in fact changed an earlier reference to *Donovan* v. *Dewey* in footnote 10. However, because of the timing, the application of this Court's decision was not briefed by either side for the Court of Appeals.

In the drug manufacturing industry, "their [warrantless inspections of commercial property] occurrence is so random, infrequent, or unpredictable that the owner, for all practical purposes, has no real expectation that his property will from time to time be inspected by government officials." 69 L. Ed. 2d at 269. Nowhere, with reference to the drug-manufacturing industry, can we find that "Congress has reasonably determined that warrantless searches are necessary to further a regulatory scheme and the federal regulatory presence is sufficiently comprehensive and defined that the owner of commercial property cannot help but be aware that his property will be subject to periodic inspections undertaken for specific purposes." 69 L.Ed. 2d, at 270. The "frequency" and "regularity" of inspections, which this Court discussed (69 L.Ed. 2d, at 272-273), does not appear in any statutory scheme for inspections of drug-manufacturing businesses.

This Court in *Barlow's* and in *Donovan* v. *Dewey* discussed the necessity of clearly defined statutory and regulatory schemes governing inspections without warrants. We believe the general language of 21 U.S.C. § 374 does not satisfy the guidelines enunciated by this Court. Indeed, the Court of Appeals referred to the lack of a clearly defined statutory or regulatory scheme for warrantless inspections or for obtaining search warrants in the drug-manufacturing industry. 651 F.2d, at 538 (fn. 6). Compare also footnote 11 of the dissent of Justice Stevens in *Barlow's* (436 U.S., at 339) that the "decision today renders presumptively invalid numerous inspection provisions in federal regulatory statutes", citing, among three examples, 21 U.S.C. § 603. That statute is a specific inspection statute relating to the food industry, which is part of the same Title 21 applicable to the inspection here.

Petitioners believe that the Court of Appeals has failed to apply standards adopted by this Court to determine what industries may be inspected without warrants. We respectfully submit that the judgment of the Court of Appeals could be summarily reversed because of its conflict with *Donovan* v. *Dewey;* in the alternative, this case presents an opportunity for this Court to give direction to the courts below for determining what industries are subject to the exceptions permitting warrantless inspections.[8] For these reasons, certiorari should be granted.

B. Are Fourth Amendment requirements inapplicable even in a criminal investigation?

At the outset of its discussion of the Morganford inspection, the Court of Appeals quotes from *Barlow's* "that '[p]robable cause in the criminal law sense is not required...' to secure a warrant for an administrative search. 436 U.S. at 320." Petitioners do not quarrel with this proposition when applied to an "administrative search", but to extend the statement to a criminal search is, we believe, not consistent with Fourth Amendment protection or the pronouncements of this Court. We respectfully suggest that certiorari should be granted to correct this egregious error.[9]

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[8] Such direction might avoid much future litigation, of which two recent cases are typical: *United States* v. *Shaefer, Michael and Clairton Slag, Inc.*, 627 F. 2d 200 (3rd Cir. 1980), and *United States* v. *Raub*, 637 F. 2d 1205 (9th Cir. 1980).

[9] Although the Court of Appeals did not expressly state that the search procedure here violated traditional Fourth Amendment guidelines, it is obvious from the Court's discussion of this issue that it was convinced that the search at Morganford could not withstand Fourth Amendment scrutiny. An examination of the record leaves no doubt.

Under the doctrine established by *Aguilar* v. *Texas,* 378 U.S. 108 (1964), and *Spinelli* v. *United States,* 393 U.S. 410 (1969), the Kendall application (Appendix G) lacks probable cause for the issuance of the Magistrate's warrant. See also the concurring opinion of Justice White in *Spinelli,* with particular reference to the discussion of *Nathanson* v. *United States,* 290 U.S. 41 (1933). The Kendall affidavit merely stated (in paragraphs 1-4) that information was available or supplied to the FDA. The sources of the information were not shown or corroborated, and there was no basis for determining the reliability

As previously noted, the Court of Appeals (at footnote 19) stated that the evidence supported the view "that the government contemplated bringing criminal charges." But the Court stated "that a warrant based on an administrative showing of probable cause is valid in this pervasively regulated industry." The anomaly in the opinion of the Court of Appeals is that a legitimate business such as the drug industry, by being characterized as a pervasively regulated industry, does not receive the constitutional protection that is afforded a participant in an illegal enterprise (e.g., gambling, illicit drugs, bank robbers, etc.). As long as the courts continue to recognize the application of the Fourth Amendment to search warrants in admittedly illegal enterprises, industries which are not per se illegal (and which are not as heavily or historically regulated as the illegal ones) are entitled to equal protection of the Fourth

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of the sources, if any. The application lacked specific details, and none of the underlying circumstances required by *Aguilar* were provided. Nor was there any indication as to when the alleged violations had taken place. There was nothing in the Kendall application from which a neutral and detached Magistrate could make his independent determination of probable cause.

The search procedure was also deficient because the decision to search and the scope of the search were left to the sole discretion of the searching officer. Cf. *United States* v. *Piner,* 608 F. 2d 358, 361 (9th Cir. 1979). The search here included all of the rooms of the premises (Mag. Tr. 19, 111), and the agents made their own determination of what to seize, without any guidelines in the warrant; they used the broadest standard of seizure (Mag. Tr. 118-120, 129-130). FDA agent Bringman testified about an "open-ended complaint" for forfeiture, which meant that anything could be seized which the agents in their judgment wanted to seize (Tr. 1039). Compare *Barlow's,* 436 U.S., at 323-324. General warrants have long been condemned. *Marron* v. *United States,* 275 U.S. 192 (1927), *Stanford* v. *Texas,* 379 U.S. 476 (1965), and *Andresen* v. *Maryland,* 427 U.S. 463, 480 (1976). For a parallel case invalidating a broad general warrant followed by on-the-spot determination similar to those made by the FDA agents here, see *Lo-Ji Sales, Inc.* v. *New York,* 442 U.S. 319 (1979).

Amendment. See concurring opinion of Justice Rehnquist in *Donovan* v. *Dewey,* 69 L.Ed. 2d, at 275, as well as questioning by Justice Rehnquist during oral argument, reported in 49 U.S. Law Week 3875.

An extension into the criminal field of the rule of *Barlow's* as to an administrative search is in conflict with numerous other decisions. In *United States* v. *Pappas,* 613 F. 2d 324, 328 (1st Cir. 1979), the Court stated:

> "The Supreme Court has sanctioned the issuance of administrative search warrants on less than probable cause, *Marshall* v. *Barlow's, Inc.,* 436 U.S. 307, 97 S.Ct. 776, 50 L.Ed. 2d 739 (1978), but has never done so in the context of a criminal or quasi-criminal proceeding."

See also *United States* v. *Lawson,* 502 F. Supp. 158 (D. Md. 1980), in which an indictment against a pharmacist for drug industry violations was dismissed for a variety of reasons. With reference to the use of an administrative inspection warrant to gather evidence for a criminal prosecution, the Court discussed numerous cases, including *Barlow's,* stating at page 165: "But once the purpose behind the search shifts from administrative compliance to a quest for evidence to be used in a criminal prosecution, the government may constitutionally enter the premises only upon securing a warrant supported by full probable cause", citing *Michigan* v. *Tyler,* 436 U.S. 499 (1978). See also *United States* v. *Shaefer, Michael and Clairton Slag, Inc.,* 637 F. 2d 200, 203-204 (3rd Cir. 1980), and *Marshall* v. *Horn Seed Co., Inc.,* 647 F. 2d 96 (10th Cir. 1981).

The opinion herein is also in conflict with *United States* v. *Device Labeled Theramatic,* 641 F. 2d 1289 (9th Cir. 1981), which is factually similar to the instant case in that it also involved an effort to seize equipment under the same provision (21 U.S.C. § 334) of the Food, Drug and Cosmetic Act as was involved here. Even though criminal proceedings were not involved, the Ninth Circuit Court of Appeals, after discussing

Barlow's and declining to extend the *Colonnade-Biswell* exception, held that "entrance into homes and offices to seize items alleged to violate the Food, Drug, and Cosmetic Act must comply with the basic requirements of the Fourth Amendment."

Not only is the opinion of the Court of Appeals in conflict with decisions of various other Courts of Appeals, but it also is contrary to numerous decisions of this Court. Aside from the unwarranted extension of the holding in *Barlow's* as to probable cause for an administrative search to the area of a criminal investigation, the Court has failed to follow, among others, *Camara* v. *Municipal Court,* 387 U.S. 523 (1967), *See* v. *Seattle,* 387 U.S. 541 (1967), *G. M. Leasing Corp.* v. *United States,* 429 U.S. 338 (1977), *Delaware* v. *Prouse,* 440 U.S. 648 (1979), and *Steagald* v. *United States,* ____ U.S. ____, 68 L.Ed. 2d 38 (1981).

The attempt of the Court of Appeals to distinguish *Michigan* v. *Tyler,* 436 U.S. 499 (1978), is unavailing; as previously noted, there is no legal basis for nullifying the Fourth Amendment for a pervasively regulated industry. We believe *Tyler* stands for the proposition that, regardless of the nature of the business involved, when investigating officials require "access to gather evidence for a possible prosecution, they may obtain a warrant only upon a traditional showing of probable cause applicable to searches for evidence of crime." Or, as Justice White, concurring, stated, "searches for criminal evidence are of special significance under the Fourth Amendment."

Finally, we believe that the Court of Appeals is in conflict with all opinions in *Donovan* v. *Dewey, supra.* Despite the holding that mining is a pervasively regulated industry, no exception was made for such an industry when the principal opinion said in footnote 6 that Fourth Amendment warrant requirements "pertain when commercial property is searched for contraband or evidence of crime." See also footnote 1 of Justice Stewart, dissenting. Justice Rehnquist, concurring in *Donovan* v. *Dewey,* stated:

> "The Court holds that warrantless searches of stone quarries are permitted because the mining industry has been pervasively regulated. But I have no doubt that had Congress enacted a criminal statute similar to that involved here — authorizing for example unannounced warrantless searches of property reasonably thought to house unlawful drug activity — the warrantless search would be struck down under our existing Fourth Amendment line of decisions. This Court would invalidate the search despite the fact that Congress has a strong interest in regulating and preventing drug related crime and has in fact pervasively regulated such crime for a longer period of time than it has regulated mining."

The Court of Appeals herein has departed from the well-entrenched protection and security which the Fourth Amendment has afforded to targets of criminal investigation in their homes, businesses, papers and effects. In so ruling, the Court of Appeals has decided an important and far-reaching federal question in a way in conflict with decisions of other Courts of Appeal and of this Court. If this decision is permitted to stand, not only will these petitioners have been deprived of Fourth Amendment protection, but many government agencies are likely to seize upon this decision as authority to deprive other citizens of their constitutional rights.

For these reasons, we respectfully suggest that certioari should be granted as to this Question.

II.

Look-alike drugs

During the trial and appellate stages in this case, the government often based both the criminal and civil forfeiture proceedings upon the fact that generic drugs marketed by petitioners looked like certain brand name drugs, and that they were similar in size, shape and color. Such evidence was introduced by the government in connection with counterfeiting and conspiracy allegations in the criminal case and also as the foundation for the civil forfeiture proceeding. Petitioners argued in the District Court and the Court of Appeals that evidence of look-alikes cannot sustain a conviction or forfeiture, but the arguments went unanswered in each Court.

It is obvious, however, from numerous references to look-alike characteristics in the opinions of the District Court and the Court of Appeals that such factors were a motivating force in the decisions for the government. For example, in the District Court's memorandum of March 29, 1979, in the criminal case (Appendix D), paragraph 9 stated: "The drug resembled Hoffman - LaRoche's Valium in size, shape and color." See also paragraph 11: "The capsules contained in the bottle were almost the same size, shape and color as Cleocin." In the July 23, 1979, memorandum in the civil forfeiture case (Appendix E), the Court spoke in paragraph 7 of the Findings of Fact of "a look-alike drug", and in paragraph 10 referred to a resemblance of size, shape, and color. (See 475 F. Supp, at 41.)

In footnote 26 of the Court of Appeals decision (Appendix A), the Court stated: "The essence of counterfeiting is the unauthorized use of the trademark, trade name or other identifying mark." (See 651 F. 2d, at 543, same footnote is No. 22.) In its discussion of Count IV with reference to Valium and Count VII as to Cleocin, the Court of Appeals also talked of similarities of size, shape and color, which it equated with counterfeiting. (See 651 F. 2d, at 544, 547.)

Thus the Court of Appeals has taken a position, with which petitioners disagree, that the marketing of look-alike drugs is a sufficient basis for a criminal conviction and a civil forfeiture. This subject of look-alike drugs is now pending before this Court in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, No. 80-2182, and *Darby Drug Co., Inc.* v. *Ives Laboratories,* *Inc.*, No. 81-11, certiorari granted October 13, 1981. See opinion below in *Ives Laboratories, Inc.* v. *Darby Drug Co.*, 638 F. 2d 538 (2nd Cir. 1981).

In the *Ives Laboratories* litigation, the issue is whether look-alike generic drugs can be the basis for a civil trademark infringement action. A fortiori, we believe that distribution of look-alike drugs cannot be the basis for the more drastic penalties of criminal convictions and condemnation and forfeiture of equipment. It is respectfully suggested that it would be appropriate for this Court to grant certiorari herein to consider this issue in conjunction with the determination of the *Ives Laboratories* litigation.

As previously noted, in its footnote 26 in Appendix A (footnote 22 in 651 F. 2d, at 543), the Court of Appeals herein said that "the essence of counterfeiting is the unauthorized use of the trademark, trade name, or other identifying mark." In so holding, the Court has extended the definition of a counterfeit drug, as contained in 21 U.S.C. § 321(g)(2), to a factual situation never intended. Section 321(g)(2) defines a "counterfeit drug" as:

> ". . .a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

There is little case authority treating this definition, although the legislative history regarding the provisions concerning counterfeit drugs is very enlightening. The *Drug Abuse Control Amendment of 1965*, P.L. 89-74, from which these provisions on counterfeiting came, was intended to control the traffic in amphetamines and barbituates. The legislative history clearly indicates that the law was never intended to apply to the manufacture of legitimate generic drugs. The purpose of the prohibition on counterfeit drugs is summed up succinctly in the Report of the Senate Committee on Labor and Public Welfare:

> "Production and distribution of counterfeit drugs are bootleg operations. Special equipment for their production such as tableting dyes, tableting punches, and capsule marking machines are secreted and put to use surreptitiously.
>
> "After being produced under conditions designedly hidden from inspection by Federal, State, and local officials, counterfeit drugs are distributed by equally devious means. These have included shipment in unmarked cartons and containers. No matter the route, however, the ultimate consumer receives a counterfeit drug in place of a trustworthy medicine. He is defrauded, and his health is jeopardized.
>
> "Because of the clandestine methods by which counterfeit drugs are manufactured and distributed and the burden they impose on interstate commerce in legitimate drugs, their regulation as contemplated by this bill, whether they are in interstate commerce or not, is absolutely essential to the effective protection of the public health."
>
> *Senate Report* No. 337 (89th Cong.), at 8.

Congressman O'Brien listed some examples of the type of traffic this bill was meant to control. See *Congressional Record,* 4421 (March 9, 1965). The history of the law strengthens an interpretation to apply it only to drugs manufactured with the intent of passing them off as the drug of another manufacturer, and not to legitimate generic drugs.

In order to be a counterfeit, a drug must falsely purport or be represented to be the product of another manufacturer, yet there was no evidence in this case to support a conclusion that any drug purported to be or was represented to be the drug of another manufacturer. It is true that the drugs in this case were similar in size, shape and color. Yet, the evidence revealed that there are a limited number of sizes, shapes and colors available (Tr. 1777), and that 95% of the products made by one manufacturer, C. M. Bundy, whose representative testified, are made to look like the original in size, shape and color (Tr. 399-400). In fact, several witnesses testified it wsa a common practice to produce drugs that look like brand name drugs, but to omit the brand name logo (Tr. 404, 472, 1254, 1257, 2107, 2146). Look-alikes are made to avoid confusion at the user level (J. Kevin Rooney, Tr. 1255).

In the instant case, none of the so-called "counterfeit" drugs had any brand name logo on them; in fact, several of the drugs had unique markings. GX-190 is a tablet with an imprint of "G-Y 250". GX-57 is a tablet with the imprint of "JM", the initials of Jamieson-McKames Pharmaceuticals. Neither of these imprints may be found on any brand name drug. The government admitted that the record clearly reflected that many generic manufacturers made look-alike drugs (Tr. 2390-A). Yet, the government contended, and the Courts seem to have found (although there was no evidence), that if a drug is similar in size, shape and color, it is a counterfeit, regardless of the absence of brand name logos or the presence of non-brand name imprints. Thus, the Courts below, by implication, have indicted the entire generic pharmaceutical industry. Such an interpretation is so overbroad and confiscatory as to be unconstitutional.

Another method of counterfeiting drugs is through fraudulent labeling. The facts here showed no such fraud. The trademarks of companies were used for easy reference and because some of the employees of doctors were not familiar with the chemical names [see witnesses Carolyn Homa (Tr. 762), Larry Malof (Tr. 1509-1510), Arlene Joyce (Tr. 1624), Dan Wiegand (Tr. 2197), Raymond Blitstein (Tr. 1335), Dr. Beckmeyer (Tr. 2068-2069), Dr. Vermilyea (Tr. 2099), Dr. Hoffman (Tr. 2123-2124), Dr. Peters (Tr. 2334), and Dr. Gushleff (Tr. 2414-2415).] The names used by petitioners were easily identifiable as generics.

GX-33-D and 174 have a label for generic Librium, chemical name Chlordiazepoxide. The label reads "Alertran 10 mg. Librium" (Tr. 906, 1783). Alertran is a trademark of petitioner Jamieson-McKames Pharmaceuticals, Inc. GX-144 is a photo of a bottle of generic valium, chemical name Diazepam. The label on that bottle reads "Valium 5 mg. Diazepam" (Tr. 1099, 1784, 2073). GX-147 and 148 are photos of bottles of petitioners' drug; the label says "Tranvil" (Tr. 1786). The label on GX-209-B is "G-Motrin" (Tr. 1643), on GX-209-D is "G-Tigan", and on GX-57 is "G-Sudafed" (Tr. 1643 and 209). The label for generic Diabinese, chemical name Chlorpropamide, as found on GX-96-E, reads "Chlorpropamide 250 mg. generic Diabinese" (Tr. 283, 574). DX-B-1 is labeled "Vaso Tabs", which is petitioners' registered generic for Vasodilan (Tr. 118). The label for generic Cleocin, chemical name Clindamycin, reads "Generic Cleocin" or "G Cleocin" (GX-96-C and 141). The evidence clearly showed that everyone handling the drugs knew that a "G" preceding a brand name indicated it was petitioners' generic drug (Tr. 850, 1503, 2196, 2224, 2249, 2252, 2295). Even FDA investigator Willis understood the "G" to stand for generic (Tr. 1473).

The government contended that the use of these names is counterfeiting per se. A label that reads "Chlorpropamide 250 mg. Generic Diabinese" clearly does not purport to be the product of Chas. Pfizer and Co., Inc. The use of these trade names was for ease of identification. It is the accepted vernacular of the generic pharmaceutical industry. None of these trade names was used to pass off these drugs as drugs of other manufacturers. Several of these drugs specifically point out that they are generics. Others have completely different names such as Triavil-Tranvil and Vasodilan-Vaso Tabs. In fact, the staff attorney for Mead-Johnson admitted that there are many listings starting with the four letters VASO in the Blue Book (Tr. 329). Several witnesses stated that it is common for a brand name and a generic name to have a close similarity. In the industry, the name would sometimes be changed a little bit so that it sounded like the brand name, but it was a little different (Tr. 1275, 2091, 2099-2100).

GX-37, the subject matter of criminal Count IV, not only revealed that it was labeled diazepam, the chemical, but it did not have the brand name logo on the tablet (Tr. 165). Although it may have looked like valium, the labeling gave assurance that it was not intended as a counterfeit, because it included the initials "JMCK" — those of petitioner Jamieson-McKames Pharmaceuticals, Inc. (Tr. 655) — and the label stated that it was from "Pharmacare Payless Pharmacy, Inc."

The basic question is whether these drugs were represented to be or purported to be the drug of another manufacturer. The evidence showed that some brand names do in fact become synonymous with the drug itself (Tr. 158). The drugs in this case carried sufficient indicia that they were not the brand name drug. A drug labeled "Generic Brand X" is in no way representing that it is Brand X's drug, but rather is denying that it is Brand X's drug. None of the above listed drugs can be considered as counterfeit. They do not comply with the definition of a counterfeit drug in 21 U.S.C. § 321(g)(2).

The last area from which evidence of counterfeiting may be discovered is the containers in which the drugs are held and shipped. The classic case, as mentioned by Congressman O'Brien, is where the drugs are packed in unlabeled bottles and bags and shipped in containers labeled as something other than drugs. Again, looking to the facts in the instant case, there was no such evidence here. If a person wished to counterfeit drugs he would not put his name, address and telephone number on the bottle, so that the FDA would know exactly where to find him. The record in this case is uncontroverted that all drugs sent out had a label on the bottle stating:

Pharmacare Generic Drugs (or)
Pharmacare Payless Pharmacy
3227 Morganford Road
776-3434

This was the business address of petitioners. Where is the representation that this is the drug of another manufacturer? No one could be led to believe that the drugs were Upjohn's, Pfizer's, or anyone else's. The only representation that was made was that these drugs came from Pharmacare Generic Drugs. In fact, the evidence established that brand name drugs were delivered with the brand name manufacturer's label (Tr. 2127).

Petitioners were not operating a bootleg operation where the manufacturing was hidden from government inspection. None of the activities Congresman O'Brien mentions are present in this case. The drugs did not have any brand name logos or monograms on them. All of these drugs were labeled with names that represented them to be anything but the drug of another manufacturer. These drugs were packaged in bottles with the name and address of the manufacturer right on the label. The distribution of these products was open and above-board, not surreptitious or clandestine.

We believe the Court of Appeals, in referring to similarities of size, shape and color as the basis for conviction and civil forfeiture, has decided federal questions pertaining to the interpretation of 21 U.S.C. § 321(g)(2) in a manner which has not been but should be settled by this Court. The Court of Appeals, we respectfully submit, has misinterpreted the statute and has declared criminal, and subject to forfeiture, acts which were never contemplated in the statutory enactment. The emphasis on similarities of size, shape and color could lead to the destruction of the entire generic drug manufacturing industry.

Inasmuch as the Court has now determined in the *Ives Laboratories* litigation to review the size, shape and color factors in relation to trademark infringement allegations, we respectfully suggest that it would be appropriate at this time to review these same factors in relation to counterfeiting and misbranding charges in the criminal and civil forfeiture areas of the law. This case presents such an opportunity.

CONCLUSION

For these reasons, it is respectfully submitted that this petition for a writ of certiorari should be granted.

Respectfully submitted,

IRL B. BARIS
611 Olive Street - Suite 2020
St. Louis, Missouri 63101
(314) 231-1312
(Counsel of record)

MARC L. SANDBERG
1015 Locust Street - Suite 1140
St. Louis, Missouri 63101
(314) 231-1884
Attorneys for Petitioners

Appendix

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Nos. 79-1367 and 79-1708

No. 79-1367

United States of America,
Appellee,

v.

Jamieson-McKames Pharmaceuticals, Inc., Pharmacare Generic Drugs, Inc., Pharmacare, Inc., Payless Pharmacy, Inc., James C. Jamieson, Sr., and James C. Jamieson, Jr.,
Appellants.

No. 79-1708

United States of America,
Appellee,

v.

All equipment including, but not limited to, an encapsulating machine not identified as to manufacturer, stainless steel coating pans, a Colton single stage rotary tablet press, a Fratelli Zanasi encapsulating machine, tablet punches and dies, which equipment is in the possession of Jamieson-McKames Pharmaceuticals, Inc., 3227 Morganford Road, St. Louis, Missouri,
Appellant.

Appeals from the United States District Court for the Eastern District of Missouri.

Submitted: February 11, 1981
Filed: May 21, 1981

Before LAY, Chief Judge, STEPHENSON and ARNOLD, Circuit Judges.

ARNOLD, Circuit Judge.

James C. Jamieson, Sr., and James C. Jamieson, Jr., individuals, and Jamieson-McKames Pharmaceuticals, Inc., Pharmacare Generic Drugs, Inc., Pharmacare, Inc., and Payless Pharmacy, Inc., corporations, appeal a judgment finding them guilty of criminal violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq. They also appeal a civil order of condemnation and forfeiture of certain drug manufacturing equipment pursuant to 21 U.S.C. §334(b). The criminal case, which resulted in convictions on one count of conspiracy to violate the Federal Food, Drug, and Cosmetic Act, and ten substantive counts of counterfeiting, misbranding, and adulterating of drugs, and the civil case were consolidated for trial before the district court[1] by consent of the parties.

The trial, which consumed more than twenty days, ended on January 17, 1978. The district court on March 29, 1979, filed its findings of fact in the criminal case. On July 23, 1979, an order, memorandum, and findings[2] were filed in the civil case. Each of the individual defendants was sentenced to imprisonment for terms of eight years and a fine of $5,000.00 on each of ten of the counts. The court suspended imposition of sentence as to count IV and placed the individuals on probation for a period of five years following the completion of the sentence of imprisonment under the other counts. Each of the four corporate defendants was fined the sum of $2,000.00 on each of the eleven counts, or $22,000.00 apiece, for a total of $88,000.00.

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[1] The Hon. John F. Nangle, United States District Judge for the Eastern District of Missouri.

[2] *United States* v. *All Equipment Including But Not Limited To An Encapsulating Machine Not Identified As To Manufacturer,* 475 F. Supp. 39 (E.D. Mo. 1979).

Asserted grounds for error are (1) that the searches and seizures conducted by the Food and Drug Administration (FDA) agents were in violation of the Fourth Amendment to the Constitution, (2) that certain statements made by the defendants to FDA agents were inadmissible because of violations of the Fifth Amendment, and (3) that the evidence was insufficient as to all criminal counts and the civil order of forfeiture and condemnation. In the main, we affirm.

I. The Facts

Jamieson-McKames Pharmaceuticals, Inc. (Jamieson-McKames) is a Missouri corporation with its principal place of business in St. Louis, Missouri. The company manufactured, purchased, packaged, labeled, distributed, and sold drugs from before June 1972 until November 1975. Jamieson-McKames sold drugs directly to doctors, clinics, and pharmacies through defendants Pharmacare, Inc., and Payless Pharmacy, Inc. Jamieson-McKames's activities were carried out by defendant James C. Jamieson, Sr.; defendant James C. Jamieson, Jr.; James C. Jamieson, III, a part-time employee; and approximately five other employees.

Jamieson, Sr., was the president and treasurer of Jamieson-McKames and a member of its board of directors. He was also a member of the board of directors and vice-president and secretary of Pharmacare Generic Drugs and during 1975 a member of the board of directors of Pharmacare.

Jamieson, Jr., a board member, vice-president, and secretary of Jamieson-McKames, was also a member of the board of directors, president, and treasurer of each of the other corporate defendants.

Defendants Pharmacare, Inc. (Pharmacare), Payless Pharmacy, Inc. (Payless) and Pharmacare Generic Drugs, Inc. (Pharmacare Generic) were also Missouri corporations engaged in the business of manufacturing, purchasing, packaging, labeling, distributing, and selling drugs. In addition, Pharmacare and Payless operated five and two retail pharmacies respectively. The operations of Pharmacare, Pharmacare Generic, and Payless were closely interrelated with each other and with those of Jamieson-McKames. For example, the two Pharmacare pharmacies doing business in doctors' offices were opened only after an agreement was reached between Jamieson-McKames and the doctors in whose offices the pharmacies operated. Jamieson-McKames stocked the pharmacies, hired their employees, paid their bills, and shared the profits with the doctors. Drugs were frequently labeled with Pharmacare Payless Pharmacy labels whether the drug was for a Payless or a Pharmacare pharmacy, or for a pharmacy unconnected with any of the defendants.

Bills owed by the pharmacies operated by Payless and Pharmacare were forwarded to their common principal place of business, which was at the same location as Jamieson-McKames's principal place of business at 3227-29 Morganford Road in St. Louis. All of Pharmacare Generic's activities were carried out by Jamieson-McKames employees. Pharmacare Generic had no employees of its own, other than corporate officers.

On October 29, 30, and 31, and November 3, 1975, federal and state agents entered and searched the premises of Jamieson-McKames Pharmaceuticals, Inc., and Pharmacare, Inc., at 3227 Morganford Road, St. Louis, Missouri. Samples of drugs were taken, documents were photocopied, quantities of drugs were embargoed, the premises and contents photographed, and machinery seized. On October 29 and 30, 1975, defendant's premises at 714 West Pierce Road, Wentzville, Missouri, were also searched, and similar items were seized.

A civil complaint for forfeiture of certain items of equipment in the defendant's possession was filed by the government in the district court on December 19, 1975, alleging that the equipment was used or designed for use in making counterfeit drugs. Jamieson-McKames Pharmaceuticals, Inc., denied the allegations in its answer filed February 19, 1976.

Thereafter, on May 12, 1977, defendants were charged in an 11-count indictment with counterfeiting, adulterating, and misbranding drugs and conspiracy to counterfeit, adulterate, and misbrand drugs. The indictment also charged that the defendants committed all of these acts with the intent to defraud and mislead, rendering such felonies punishable under 21 U.S.C. §333(b).

II. The Fourth Amendment

The appellants contend that their Fourth Amendment rights were violated by the failure of the court to suppress evidence seized by government agents from the defendants' business premises at Wentzville, Missouri, and at the Morganford Road site in St. Louis, and from a building in St. Louis operated by the Chambers Medical Group.

The Wentzville Search

The seizures at the Wentzville pharmacy were conducted on the authority of a notice to inspect authorized by 21 U.S.C. §374(a).[3] The employee in charge was given a copy of the notice to inspect, but no warrant to inspect was obtained.

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[3] 21 U.S.C. §374(a) provided in part at the time relevant to this case:

> (a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being

The Supreme Court has held that warrantless searches are generally unreasonable, and that commerical premises as well as homes are within the Fourth Amendment's protection. *Marshall* v. *Barlow's, Inc.*, 436 U.S. 307, 312 (1978). An exception from the search-warrant requirement has, however, been delineated for industries "long subject to close supervision and inspection," *Colonnade Catering Corp.* v. *United States*, 397

> used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment date, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this chapter), and (E) research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (j) or section 357(d) or (g) of this title, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Samples may be taken during the inspection. See 21 U.S.C. §§374(c), (d).

U.S. 72, 77 (1970), and "pervasively regulated business[es]," *United States* v. *Biswell*, 406 U.S. 311, 316 (1972). *Colonnade* involved the liquor industry, and *Biswell* the interstate sale of firearms. The threshold question therefore is whether the drug-manufacturing industry should be included within this class of closely regulated businesses.

The appellants argue that the drug-manufacturing industry is no more closely regulated than any number of industries involved in interstate commerce, and that therefore the rule of *Marshall* v. *Barlow's Inc., supra,* requiring a warrant in the absence of consent before an administrative search can take place, should apply. In *Barlow's,* the Supreme Court held that warrantless searches authorized by §8(a) of the Occupational Safety and Health Act, 29 U.S.C. §657(a), violated the Fourth Amendment. There, however, the government sought to inspect work areas not open to the public on the premises of an electrical and plumbing contractor. In *Barlow's* the argument that all businesses involved in interstate commerce had "long been subject to close supervision" of working conditions was urged by the Secretary of Labor but explicitly rejected by the Court. In rejecting this argument and others the Court specifically preserved the *Colonnade-Biswell* exception to the warrant requirement. The Court indicated that there were other industries, covered by regulatory schemes applicable only to them, where regulation might be so pervasive that a *Colonnade-Biswell* exception to the warrant requirement could apply. 436 U.S. at 313, 321.

Such warrantless searches are upheld because "when an entrepreneur embarks on such a business, he has chosen to subject himself to a full arsenal of governmental regulation," *id.* at 313, and " 'in effect consents to the restrictions placed on him'." *Ibid.*, citing *Almeida-Sanchez* v. *United States,* 413 U.S. 266, 271 (1973). Further, in the face of a long history of government scrutiny, such a proprietor has no "reasonable expectation of privacy." *Ibid.*

We think the drug-manufacturing industry is properly within the *Colonnade-Biswell* exception to the warrant requirement. The drug-manufacturing industry has a long history of supervision and inspection. The present Food, Drug, and Cosmetic Act has its origins in the Food and Drug Act of 1906, 34 Stat. 768. That Act was an attempt by Congress "to exclude from interstate commerce impure and adulterated food and drugs . . ." and to prevent the transport of such articles "from their place of manufacture." *McDermott* v. *Wisconsin,* 228 U.S. 115, 128 (1913).

The *Biswell* Court acknowledged that the history of regulation of interstate firearms traffic was "not as deeply rooted" as the history of liquor regulation, but included firearms within the warrant exception because their regulation was of "central importance to federal efforts to prevent violent crime and to assist the states in regulating the firearms traffic within their borders." *United States* v. *Biswell, supra,* 406 U.S. at 315. This passage teaches that the nature of the federal or public interest sought to be furthered by the regulatory scheme is important to our analysis. See *Marshall* v. *Barlow's, Inc., supra,* 436 U.S. at 337 (Stevens, J., dissenting). It is difficult to overstate the urgent nature of the public-health interests served by effective regulation of our nation's drug-manufacturing industry. Furthermore, virtually every phase of the drug industry is heavily regulated, from packaging, labeling, and certification of expiration dates,[4] to prior FDA approval before new drugs can be marketed.[5] The regulatory burdens on the drug-manufacturing industry are weighty, and that weight indicates that the drug manufacturer accepts the burdens as well as the benefits of the business and "consents to the regulations placed on him." *Marshall* v. *Barlow's, Inc., supra,* 436 U.S. at 313.

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[4] See 21 U.S.C. §§351 and 352 which deal, inter alia, with adulterated drugs and devices (§351 generally), adequate controls in manufacture (§351(a)), strength, quality, or purity (§351(b)), false or misleading labeling (§352(a)), certification of certain drugs (§352(k) and (l)), color additives (§352(m)) and prescription drug advertising (§352(n)).

The final lesson of *Barlow's* is that the reasonableness of warrantless searches is dependent on the "specific enforcement needs and privacy guarantees of each statute." *Id.* at 321. In *Barlow's* the Court was unconvinced that requiring OSHA officials to obtain administrative warrants when consent to inspect was withheld would cripple the effectiveness of the enforcement scheme. The Court reasoned that most businessmen were likely to consent to inspections, and the Secretary's argument that a warrant requirement would impede enforcement was inconsistent with the fact that OSHA regulations promulgated by the Secretary themselves provided for obtaining warrants, even though the statute did not require it. *Id.* at 316-20. This Court is aware of no similar FDA regulation.[6]

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[5] See 21 U.S.C. §355, which outlines the requirements for new-drug applications, filing procedures, exemptions, records and reports, etc. In addition, every drug manufacturer must register with the Secretary of Health and Human Services on or before December 31 of each year, 21 U.S.C. §360(b), and the failure to register is a crime, 21 U.S.C. §331(p).

[6] While it is true that the Morganford Road inspection, to be discussed below, was conducted pursuant to an administrative warrant obtained six days prior to the actual search, this fact does not necessarily weaken the FDA's argument that warrants as a matter of policy should not be required. The fact that a warrant was obtained on one occasion does not mean that it is practicable to do so in every instance. More important for our analysis, and seemingly also for the Court in *Barlow's,* is the existence *vel non* of formal regulations that are inconsistent with the stated needs of enforcement. We find none here.

Regulation of the drug industry differs from the OSHA situation in another significant way. The class sought to be protected by OSHA regulation of safety of work areas is made up of employees, who are in the work place itself and free to report violations at any time.[7] The protected class in the area of drug manufacturing is the consuming public, which has no way of learning of violations short of illness resulting from the consumption of defective drug products. In this sense the enforcement needs of drug-industry regulation are considerably more critical than those before the Court in *Barlow's.*

As for privacy guarantees, the Supreme Court points out that a warrant provides assurances that the proposed "inspection is reasonable under the Constitution, is authorized by statute, and is pursuant to an administrative plan containing specific neutral criteria." *Id.* at 323 (footnote omitted). The notice of inspection used in this case satisfies at least some of these criteria. It informs the "owner or agent in charge" (§374(a)) of the "scope and objects of the search." *Barlow's, supra,* 436 U.S. at 323. Although the notice of inspection makes no express reference to reasonableness under the Constitution, it clearly states that notice is given pursuant to 21 U.S.C. §374, which is enacted by the Congress. The name of the firm and address is also prominently listed. Further, the notice of inspection reproduces large portions of §374(a), stating the areas and objects to be searched; that the inspection is to take place at reasonable times; that certain records are to be made available to the inspector; that each inspection must be made with reasonable promptness; that each inspection must be accompanied by a separate notice; and that the purpose of any inspection of a prescription-drug operation is discovery of information "bearing on whether prescription drugs [are being] adulterated or misbranded within the meaning of" the Act or on other violations of the Act.[8] 21 U.S.C. §374(a). Equally important, the Notice of Inspection informs the owner of what cannot be examined by the inspector. Inspections relating to prescription drugs do not extend to financial data, pricing data, and certain data regarding sales, personnel, and research.[9] *Ibid.*

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[7] "29 U.S.C. §657(f)(1) provides that employees or their representatives may give written notice to the Secretary of what they believe to be violations of safety or health standards and may request an inspection." *Barlow's, supra,* 436 U.S. at 320 n.16. We consider it less likely that violations of the kind involved in this case will be reported to the FDA by employees of the drug manufacturers.

In sum, the authorizing statute now before the Court was not painted with so broad a brush as the one rejected in *Barlow's*, the enforcement needs are more critical in the drug-manufacturing field, and the interests of the general public are more urgent. We hold that inspections authorized by §374 are "reasonable" and therefore not inconsistent with the Fourth Amendment. Thus, this case falls within the "carefully defined classes of cases" which are an exception to the search-warrant requirement.[10] *Camara* v. *Municipal Court*, 387 U.S. 523, 528

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[8] See note 2 *ante* for the pertinent portion of §374(a) contained in the notice to inspect.

[9] The Court in *Barlow's* noted that "[d]elineating the scope of a search with some care is particularly important where documents are involved." *Barlow's, supra,* 436 U.S. at 324 n.22. We are persuaded that §374(a) shows some sensitivity to this concern.

[10] Several courts have addressed this or similar issues. In accord with our conclusion is *United States* v. *New England Grocers Supply Co.*, 488 F. Supp. 230 (D. Mass. 1980). This case involved evidence seized during inspection of a food-supply warehouse pursuant to §374. *United States* v. *Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976), decided prior to *Barlow's*, found warrantless searches authorized by §374 to be consistent with those allowed in *Biswell*. *United States* v. *Business Builders, Inc.*, 354 F. Supp. 141 (N.D. Okla. 1973), was another pre-*Barlow's* case involving food. Relying on *Biswell*, the court said:

(1967). We share, to a degree, the fears expressed by appellants that many businesses are thoroughly regulated by the United States, and that an undue extension of our rationale might obliterate much of the Fourth Amendment's protection. On balance, however, we are persuaded that the capacity for good or ill of the manufacture of drugs for human consumption is so great that Congress had power to enact §374(a).

> It would be an affront to common sense to say that the public interest is not as deeply involved in the regulation of the food industry as it is in the liquor and firearms industries. (Footnote omitted). One need only call to mind recent cases of deaths occurring from botulism. Modern commerce has devised such an efficient and rapid means of distribution of food products to the consumer that a batch of contaminated food may cause widespread illness and death before the public can be warned and the contaminated products removed from the market.

354 F. Supp. at 143. In *United States* v. *Del Campo Baking Mfg. Co.*, 345 F. Supp. 1371 (D. Del. 1972), still another food case, the court considered the regulatory scheme under the Federal Food, Drug, and Cosmetic Act to be as pervasive as the licensing scheme in *Biswell*. Post-*Biswell* cases holding a search warrant required in the absence of consent include *United States* v. *Roux Laboratories*, 456 F. Supp. 973 (M.D. Fla. 1978) (where consent refused, a warrant is necessary). See also *United States* v. *Litvin*, 353 F. Supp. 1333 (D.D.C. 1973), considering a motion to suppress evidence seized during a routine inspection of a food warehouse. The court treats the food industry as a closely regulated one but requires a warrant when consent to inspect is withheld. Compare the discussion of *Colonnade* in text *infra*. *But cf. Marshall* v. *Dewey*, 493 F. Supp. 963 (E.D. Wis. 1980) (mining industry not within the *Colonnade-Biswell* exception), *prob. juris. noted*, 101 S. Ct. 937 (1981) (No. 80-901).

Having concluded that drug manufacturing is a "pervasively regulated" industry does not end our inquiry,[11] but establishes only that Congress has broad authority to place restrictions on that industry that might otherwise violate the Fourth Amendment. A question remains as to whether the conduct of the government in this case conforms with the statutory scheme provided by the Congress.

The Court in *Colonnade Catering Corp.* v. *United States, supra,* confronted a very similar issue. There Internal Revenue Service agents, suspecting a violation of the federal excise tax law, sought to inspect an establishment where liquor was being served.[12] The owner refused to open a locked storeroom and asked if the agents had a search warrant. The agents answered that they didn't need a warrant, broke the lock, entered, and found evidence of regulatory violations.

After emphasizing the long history of regulation of the sale of liquor, the Court acknowledged the broad authority of Congress to provide for inspections under the liquor laws. *Colonnade, supra,* 397 U.S. at 75-76. Under the existing statutory scheme, however, the Court concluded that Congress had not provided for "forcible entries without a warrant," *id.* at 77. This conclusion was based on Congress's provision of a separate penalty for a dealer's refusal to permit an inspection.[13] Compare *Biswell, supra,* 406 U.S. at 314. Consent being absent, the search was held invalid, and the evidence suppressed.

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[11] Other courts have held the pharmaceutical industry "pervasively regulated" under the Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. §§801 *et seq. United States* v. *Schiffman,* 572 F.2d 1137 (5th Cir. 1978), held that "[t]he pharmaceutical industry is a 'pervasively regulated business' like the liquor and gun industries," *id.* at 1142, citing *United States* v. *Montrom,* 345 F. Supp. 1337, 1340 (E.D. Pa. 1972), *aff'd mem.,* 480 F.2d 918, 919 (3d Cir. 1973).

[12] The Secretary of the Treasury and his agents have broad authority to inspect retail liquor establishments under 26 U.S.C. §5146(b) and 26 U.S.C. §7606.

The Federal Food, Drug, and Cosmetic Act contains provisions, similar to those addressed in *Colonnade,* which punish refusals to permit inspections by imprisonment up to one year, or a fine of not more than $1,000, or both. 21 U.S.C. §§331(f) and 333(a).[14] It follows, therefore, as in *Colonnade,* that an inspection pursuant to a §374 notice to inspect is authorized only when there is a valid consent. If consent is withheld, a separate violation of the Act occurs, and the FDA inspectors are required to obtain a warrant before the inspection can proceed.

This brings us to the problem presented by the search at the Wentzville site. Here, as in *Colonnade,* the critical issue is whether there was consent to the inspection.[15] Unfortunately this issue was not expressly resolved in the court below. The magistrate approved the Wentzville inspection but made no findings on the consent issue.[16] Although there is evidence in the record from which consent could have been found, the trier of fact was not required to believe it, and we are not at liberty to make our own findings. Therefore, as to Counts VII and VIII, the counts as to which evidence was taken from the Wentzville site, the judgments of conviction will be vacated, and the cause remanded for the making of further findings on the issue of consent. The district court may hold a further hearing on this issue if it wishes, but the existing record may be sufficient.

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[13] 26 U.S.C. §7342.

[14] 21 U.S.C. §331(f) provides:

> The following acts and the causing thereof are prohibited:
>
> (f) The refusal to permit entry or inspection as authorized by section 374 of this title.

21 U.S.C. §333(a) provides:

> §333. Penalties-Violation of section 331 of this title
>
> (a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

[15] See *United States* v. *Litvin,* 353 F. Supp. 1333 (D.D.C. 1973), where the court distinguished *Biswell* on this basis. See also *United States* v. *Kramer Grocery Co.,* 418 F.2d 987 (8th Cir. 1969). This case affirmed a ruling that valid consent was necessary before FDA had authority to conduct a warrantless inspection under §374. Although the rationale of *Kramer* is inconsistent with our reading of the later-decided cases of *Colonnade* and *Biswell,* the holding of *Kramer* is still valid in the food and drug areas.

The Morganford Road Inspection

The inspection and seizures conducted at the Morganford Road site were supported not only by a statutory notice, but also by a Warrant for Inspection issued by a United States Magistrate on October 23, 1975, and a Warrant for Arrest of Property issued by the clerk of the district court on October 29, 1975.[17] Appellants now argue that the inspection and seizures were illegal because the application for the warrant for inspection did not comply with traditional probable-cause standards. *Marshall* v. *Barlow's, Inc., supra,* however, teaches that "[p]robable cause in the criminal law sense is not required . . ." to secure a warrant for an administrative search. 436 U.S. at

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[16] The district court adopted the magistrate's recommendation. It relied on *Biswell,* but that case is not dispositive as to the Wentzville site, because under the *Colonnade* analysis described above, if consent is refused after a notice of inspection is served, the refusal of consent may be separately prosecuted, but entry cannot be forced without a warrant. This result follows not because Congress *could not* authorize entry under a notice of inspection over objection, but because, in the food-and-drug area, just as in the liquor area, it *has not* done so.

[17] Although 21 U.S.C. §374 authorizes FDA agents to take samples of drugs during an inspection, an in rem action is required if large quantities of drugs or equipment are to be seized. For this reason the FDA obtained the Warrant for Arrest of Property pursuant to 21 U.S.C. §334(a)(1), which provides procedures closely conforming to those in admiralty.

320. Probable cause for administrative-search purposes may be based on "specific evidence of an existing violation," *ibid.* (footnote omitted), or a "showing that 'reasonable legislative or administrative standards for conducting an . . . inspection are satisifed with respect to a particular [establishment].' " *Ibid.*, citing *Camara* v. *Municipal Court,* 387 U.S. 523, 538 (1967). Those standards are met here, where the application for the inspection warrant contained evidence of numerous violations of the FDCA, sworn to by an FDA investigator.[18]

Appellants next argue that the inspections were part of an ongoing criminal investigation, and that therefore a warrant issued on less than criminal probable cause was not sufficient to authorize a search.[19] It is our view that a warrant based on an administrative showing of probable cause is valid in this pervasively regulated industry. To hold otherwise would be inconsistent with our conclusion, already expressed, that warrantless entry under a notice of inspection does not violate the Fourth Amendment in the drug-manufacturing field. Probable-cause standards are relaxed because the business person engaged in this industry has a lesser expectation of privacy.

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[18] The application stated that the FDA had information that Jamieson-McKames had received magnesium salicylate tablets from outside the State of Missouri which were made to look like Motrin, a drug manufactured by the Upjohn Company; that the drugs were repacked into bottles labeled with the Motrin brand name; that the FDA had other information indicating Jamieson-McKames packaged or manufactured other drugs which resembled brand-name drugs in shape and appearance; and that Jamieson-McKames was marketing drugs that required prior administrative approval when no applications for approval were on file with the FDA.

[19] There was evidence that the FDA investigators were accompanied by law-enforcement officers from the State of Missouri. Also, on several occasions prior to the Morganford Road inspection FDA agents made undercover buys of defective drugs at various pharmacies owned by the appellants. The appellants argue that there can be little doubt that the government contemplated bringing criminal charges. The evidence supports this view.

The appellants cite *Michigan* v. *Tyler,* 436 U.S. 499, 512 (1978), for the proposition that where the government has probable cause to believe that a crime has been committed, access to gather evidence for a criminal prosecution requires a warrant issued upon a traditional showing of probable cause. *Tyler* involved a series of searches by a fire marshal at the scene of a fire. During the initial inspection two containers of flammable liquid were found. Suspecting arson, the fire chief summoned police and turned over the containers. Later that day the marshal, continuing his initial investigation, discovered suspicious burn marks on some carpet and other evidence of arson. Some weeks later fire officials returned to the premises on several occasions to gather evidence. The Supreme Court held that

> an entry to fight a fire requires no warrant, and that once in the building, officials may remain there for a reasonable time to investigate the cause of the blaze. Thereafter, additional entries to investigate the cause of the fire must be made pursuant to the warrant procedures governing administrative searches. Evidence of arson discovered in the course of such investigations is admissible at trial, but if the investigating officials find probable cause to believe that arson has occurred and require further access to gather evidence for possible prosecution, they may obtain a warrant only upon a traditional showing of probable cause applicable to searches for evidence of a crime.

Id. at 511-12 (citiations omitted).

The answer is that *Tyler* did not involve pervasively regulated industries, which the Supreme Court has referred to as "exceptions" that are "responses to relatively unique circumstances." *Barlow's,* 436 U.S. at 313. The rule in *Tyler* rests on a different foundation from the rule applicable to pervasively regulated industries. In *Tyler* the Court said

> there is no diminution in a person's reasonable expectation of privacy nor in the protection of the Fourth Amendment

> simply because the official conducting the search wears the uniform of a firefighter rather than a policeman, ...

436 U.S. at 506. In the case of the inspection to discover the cause of a fire, the reasonable expectation of privacy remains, but the basis for the pervasively-regulated-industry exception to the warrant requirement is that there is no reasonable expectation of privacy. See *Barlow's,* 436 U.S. at 313. Therefore, *Tyler* is not determinative.

For these reasons we hold that in the case of a pervasively regulated industry warrants based on an administrative showing of probable cause are valid so long as the extent of the intrusion is limited to the purposes specified in the statute.[20] In *Barlow's* the Supreme Court indicated that specific evidence of an existing violation (and the FDA had such evidence here) could justify a search based upon an administrative warrant, even though OSHA contains criminal as well as civil penalties. See 29 U.S.C. §666. Thus the evidence from the Morganford Road site was not seized in violation of the Fourth Amendment and was properly admissible at trial.[21] The question of consent, discussed above with respect to the Wentzville site, does not arise here, because the agents did obtain a warrant based on a valid administrative showing.

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[20] A different issue would be presented where inspectors used their regulatory authority to gather evidence of a crime or violation outside the scope of the authorizing statute. That case is not presented here, where only violations of the FDCA were prosecuted.

[21] We have considered and hold to be without merit appellants' statutory argument that searches of pharmacies here were invalid under 21 U.S.C. §374(a)(1). Appellants' pharmacies were closely related to their manufacturing activities.

The Chambers Medical Group Search

During the course of the trial an issue arose concerning several searches of a dispensary in the ground-floor area of the Chambers Medical Group building in St. Louis, owned by a Dr. Salit. Appellants question the legality of these searches.

A Dr. Eckert testified that he and Dr. Salit were "partners" in a "corporation" engaged in the practice of medicine in the building. The doctors made arrangements with Jamieson, Jr., to open a dispensary on the lower floor of "their" building. Jamieson, Jr., was to pay rent, hire employees, pay for the utilities, stock the dispensary, and pay all other ancillary expenses, and at the end of each month the profits were to be divided between the doctors' corporation and Jamieson, Jr. There was further testimony that the dispensary ceased doing business on October 29, 1975, after there were reports in the press of the searches at Morganford Road. During and after the period when the dispensary was operating (roughly April 1975 to October 29, 1975), both doctors and their employees had unlimited access to the dispensary and had their own keys.

The agent who conducted the searches testified that he visited the store on November 7, 10, 11, 12, 14, 17, and 24, 1975. He also testified that after he presented his credentials Dr. Eckert let him in and gave permission to collect samples. The district court ruled that Dr. Eckert had capacity to consent to the search and that he did give his consent to the FDA inspector. The lower court's ruling was based on *United States* v. *Matlock*, 415 U.S. 164 (1974), in which the Supreme Court said

> proof of voluntary consent [to a warrantless search], . . . is not limited to proof that consent was given by the defendant, but may show that permission to search was obtained from a third party who possessed common authority over or other sufficient relationship to the premises or effects sought to be inspected.

Id. at 171 (footnote omitted).

We agree with the district court. The agent obtained entry to the dispensary area after Dr. Eckert "offered him a key," and there were no threats or overbearing assertions of authority. The doctors and Jamieson, Jr., were in effect in business together, and Dr. Eckert's authority to consent to the searches cannot be seriously questioned. Therefore the searches at the Chambers Medical Group building were not in violation of the Fourth Amendment.

III. *Miranda* Warnings

Appellants next argue that certain statements made by the defendants to FDA agents during the searches were inadmissible at trial because *Miranda* warnings were not given. See *Miranda* v. *Arizona,* 384 U.S. 436 (1966). The district court held that *Miranda* was not applicable because "the evidence failed to establish that defendants . . . were in a custodial situation, subject to arrest."

Evidence presented at trial showed that FDA agents are without authority to make arrests, that the defendants' movements were not restricted during the time of the search, and that there were no threats or coercion. Evidence also indicated that appellants' employees were free to go about their business, and that consultation with attorneys was not limited. There is ample evidence to support the district court's finding, and the statements were therefore properly admitted at trial.

IV. Sufficiency of the Evidence

Appellants next argue that there was insufficient evidence to support conviction of any of the 11 counts charged. The substantive counts II through XI will be discussed first, with the conspiracy charge, count I, discussed last.

Count II

Count II of the indictment alleged, and the district court found, that the defendants sold counterfeit Motrin tablets to a

Dr. Zack Barnes of Kansas City, Missouri, with the intent to defraud and mislead. See 21 U.S.C. §§321(g)(2), 331(i)(3), and 333(b). A "counterfeit drug" is defined as

> a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer . . . other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of . . . such other drug manufacturer . . ..

21 U.S.C. §321(g)(2). "Motrin" is the trademark of the Upjohn Company used for the drug ibuprofen since 1970. Upjohn has never authorized any of the defendants to manufacture ibuprofen or to use the trademark Motrin. Since October 1974, Upjohn has manufactured and distributed Motrin tablets, which are coated, round, orange tablets with the logo "Upjohn 750" on one side. When Motrin was first marketed, demand exceeded supply, resulting in a nation-wide shortage from late 1974 until late 1975. During the Motrin shortage in June of 1975, Jamieson, Jr., ordered and received 200,000 magnesium salicylate tablets from C.M. Bundy Company of Cincinnati, Ohio. At Jamieson, Jr.'s, request C.M. Bundy manufactured the tablets to resemble a Motrin tablet. Sometime after this, in response to an order by Dr. Zack Barnes, Jamieson-McKames sent Dr. Barnes a bottle with "Motrin" printed on a Pharmacare Payless label, thereby falsely representing the contents as Motrin.[26]

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[26] The FDA analysis established that the drug contained no ibuprofen. The fact that the tablets did not contain Motrin's active ingredient, ibuprofen, is not relevant to the charge of counterfeiting. The essence of counterfeiting is the unauthorized use of the trademark, trade name, or other identifying mark. Thus, even if the tablets were chemically indistinguishable from Motrin, counterfeiting could still be found.

We affirm the trial court's judgment of conviction on count II. Where a trial, like this one, is to the court rather than a jury, the standard of review is "whether there is substantial evidence, taking the view most favorable to the government, to support the fact determination by the trial court." *United States* v. *Cady,* 567 F.2d 771, 774 (8th Cir. 1977), *cert. denied,* 435 U.S. 944 (1978); *United States* v. *Marly,* 549 F.2d 561, 563 (8th Cir. 1977). This standard is more than adequately met for count II.

Count III

Count III charged, and the district court found, that the defendants caused the misbranding of magnesium salicylate tablets as "Motrin formula" while they were held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§331(k) and 333(b). A drug is "misbranded" "[i]f its labeling is false or misleading." 21 U.S.C. §352(a).

Magnesium salicylate tablets were shipped in bulk in interstate commerce by C.M. Bundy of Cincinnati, Ohio, to the appellants, who then packed the tablets in bottles labeled "Motrin formula." There was testimony that the "Motrin formula" label represented the tablets to be products of the Upjohn Company and to contain ibuprofen, both of which representations proved to be false. There was further testimony of FDA investigators who presented prescriptions for Motrin at various pharmacies operated by appellants that they were sold magnesium salicylate tablets instead.

It is noteworthy that the above listed incidents were not isolated ones, according to evidence presented at trial. There was testimony that the appellants made similar shipments to a Pharmacare pharmacy in St. Clair, Missouri, and to the Chambers Group dispensary, where the tablets were routinely dispensed as Motrin. This pattern is important, because 21 U.S.C. §333(b) provides for more severe penalties for violations of the Act accompanied by the intent to defraud or mislead. The trial court's finding on this element of the crime is more than amply supported by the record. The judgment of conviction on count III is affirmed.

Count IV

Count IV of the indictment alleged that the appellants held for sale counterfeit "Valium" with the intent to defraud and mislead in violation of 21 U.S.C. §§331(i)(3) and 333(b). The district court found that the appellants sold and held for sale bottles of diazepam tablets which bore the trademark "Valium," a trademark held by Hoffman-LaRoche, Inc., which never authorized its use by the appellants.

It was stipulated at trial that appellants were not authorized to use the trademark or to manufacture diazepam. The government also introduced at trial a bottle labeled "Valium" that was seized in the retail section of the pharmacy on Morganford Road. The tablets were virtually the same size, shape, and color as the Hoffman-LaRoche product. Jamieson-McKames obtained bulk diazepam from Gyma Laboratories, and the tablets were then manufactured at Morganford Road and labeled as valium. Jamieson, Sr., was said to have made "Valium" two to four times a month during the period between 1972 and the time of the inspection in October of 1975.

There is ample evidence to sustain the convictions on count IV, especially considering the frequency and duration of the violations. The appellants' use of diazepam contrary to the patent seemed to be a calculated effort to substitute their product for the brand-name drug. The district court's judgment of conviction on count IV is affirmed.

Count V

Count V of the indictment charged the appellants with causing the adulteration of a drug held for sale with the intent to defraud and mislead in violation of 21 U.S.C. §§331(k) and 333(b). A drug is "adulterated"

> if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . ..

21 U.S.C. §351(a)(2)(B). If the drug is not recognized in an official compendium, it is also adulterated if its "strength differs from, or its purity or quality falls below, that which it purports or is represented to possess." 21 U.S.C. §351(c).[27]

Evidence presented at trial tended to show the following: In January 1975, pursuant to an order from Pharmacare Generics, a shipment of potassium phenoxymethyl penicillin (pen V) with an expiration date of August 1975, was sent from Zenith Laboratories in New Jersey to appellants' place of business in St. Louis, Missouri. During the ensuing months up to the time of the inspections at Morganford Road, bottles of pen V were relabeled. The replacement labels bore the name Pharmacare Generic, Inc., rather than Zenith Laboratories, Inc., and read in part, "Cheri-Penn" . . ., "Flavored Potassium Penicillin G" . . ., "Exp. Date: 7/77." No records were kept of this relabeling procedure.

During the FDA inspections at the Morganford site the pen V bottles were found in the wholesale section of the pharmacy. One of the boxes with a Zenith pen V label on the outside contained 18 bottles with Pharmacare Generic labels. The Pharmacare Generic labels represented that the bottles contained potassium penicillin G (pen G).

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[27] Appellants were charged in Count V under §351(c) as well as under §351(a)(2)(B), because Cherri-Penn flavored Potassium Penicillin powder, the drug involved, is not recognized in an official compendium, the United States Pharmacopeia.

Our examination of the record reveals evidence of the appellants' failure to keep records of the receipt, repacking, and labeling of the pen V. This evidence supports a conviction under §351(a)(2)(B) because of a lack of conformity "with current good manufacturing practice."[28] Evidence presented also supports conviction under §351(c), because the bottles in question contained pen V rather than pen G, thus rendering the strength and purity of the substance different from what the labels represented. We therefore affirm the judgment of conviction on Count V.

Count VI

Count VI also involves the appellants' relabeling of the bottles of pen V. According to the indictment the drugs labeled, in part, "Flavored Potassium Penicillin G Powder" . . ., "Exp. Date 7/77," were in violation of §352(a), which deems a drug misbranded if its label is false or misleading. The drug was also said to be misbranded under §352(*l*), in that it was represented to be composed of penicillin, at least in part, and there was no certificate in effect as to the drug.[29]

Evidence presented at trial indicated that in January 1975 the appellants purchased bottles of pen V powder which was certified until August 1975. There was testimony that such a product could be obtained at a reduced price because the expiration date was so near. Jamieson, Jr., was said to have directed Jamieson-McKames employees to replace the pen V labels with pen G labels and to extend the expiration date to July 1977. The expiration date on the label of the "Flavored Potassium Penicillin G Powder" was not approved by the FDA and was not based on stability testing, as required by 21 C.F.R. §432.5(a)(3).

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[28] Appellants' argument that §351(a)(2)(B) is unconstitutionally vague is without merit. The constitutionality of the statute was upheld against a vagueness charge in *United States* v. *Article of Drug*, 484 F.2d 748 (7th Cir. 1973). In addition, interpretive regulations have been promulgated by the Secretary. Specifically, 21 C.F.R. §211.80 describes proper record-keeping procedures for packaging and labeling operations. These standards are clear and have not been met by the appellants.

[29] 21 U.S.C. §357 requires that all drugs containing penicillin be certified as to strength, quality, and the like, and be assigned an expiration date.

This evidence supports a conviction of misbranding under 21 U.S.C. §352(l), in that the drug contained penicillin and was not properly certified. Although, as originally labeled, the drug was certified by the FDA, the certificaiton ceased to be effective when the labeling was altered. 21 C.F.R. §431.11(a)(2). The drugs were also misbranded within the meaning of §352(a) because their labels were "false or misleading." The evidence established that the expiration date was false, and that the bottles did not contain pen G as represented on the label. The evidence is sufficient under either of the above provisions.

Appellants argue that there was insufficient evidence to show that the bottles of pen G were "held for sale" as required by 21 U.S.C. §331(k). The argument is based on considerable testimony at trial indicating that the section of the pharmacy in which the pen G bottles were stored was a designated quarantine area reserved for products that were not for sale. This testimony was not uncontradicted, however. One former employee testified that she never heard that section of the pharmacy referred to as a quarantine area. An FDA inspector also testified that one of the pharmacists, Mr. Abelson, told him during the inspection that all drugs in the section were to be sold. The inspector testified further that there were no signs designating a quarantine area. The record is sufficient to support the trial court's finding that the drugs were being held for sale. The statute does not require that sales actually take place. The trial court found that appellants purchased bottles of a soon-to-expire drug, removed the labels, and replaced them with labels bearing false information. Inferring from these facts an intent to market the drugs is only common sense.

Appellants next argue that counts V and VI involve identical proof, and that therefore the district court erred in permitting prosecution of both counts based on the same conduct. They point out that both counts are laid under the same statutes, 21 U.S.C. §§331(k) and 333(b).

This argument is contrary to *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964), which specifically dealt with the scope of §331(k). There the Court said:

> The language of §[331(k)] unambiguously defines two distinct offenses with respect to food held for sale after interstate shipment. As originally enacted in 1938, the subsection prohibited "[t]he alteration, mutilation, destruction, obliteration, or removal" of the label, or "the doing of any other act" with respect to the product which "results in such article being misbranded." The section was amended in 1948 to prohibit additionally "the doing of any other act" with respect to the product which "results in such article being adulterated."

Id. at 89 (footnotes omitted).[10] Thus, it is clear that separate prosecutions for misbranding drugs and adulterating drugs are consistent with the intent of Congress and are within the language of the statute. Nor do counts V and VI conflict with the rule of *Blockburger* v. *United States,* 284 U.S. 299, 304 (1932):

> The applicable rule is that where the same act or transaction constitutes a violation of two distinct statutory provisions, the test to be applied to determine whether there are two offenses or only one, is whether each provision requires proof of a fact which the other does not.

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[10] Although *Wiesenfeld* was a prosecution involving adulterated food, the statute applies with equal force to drugs.

The proof required by count V involved, among other things, lack of conformity with good manufacturing practices by failure to keep adequate records of the relabeling process. This conduct comes within "the doing of any other act" which "results in such article being adulterated." 21 U.S.C. §331(k). The misbranding charged in count VI was proved by evidence of "alteration of the labeling" that rendered the label false or misleading. These crimes are distinct, and different facts were proved to support conviction. For example, had the appellants removed the Zenith Laboratories labels and replaced them with Pharmacare labels which were accurate in every way, the failure to keep records of the relabeling process would still support a charge of adulteration. The government need not prove that the labels were false or misleading as required for a misbranding charge, but only that current good manufacturing practice was not followed.

There is ample evidence in the record to support the judgment of conviction on count VI.

Counts VII and VIII

Count VII of the indictment alleged and the district court found that the appellants held for sale counterfeit Cleocin tablets. "Cleocin" is the trademark of the Upjohn Company for the drug clindamycin hydrochloride. Upjohn also holds the patent for clindamycin. Count VII is based on a bottle with a Pharmacare Payless label, labeled "300 Cleocin 150 mg.," which was held for sale at the Wentzville pharmacy. The bottle was said to be a "counterfeit drug" because its label bore the trademark "Cleocin" without the authorization of the Upjohn Company. 21 U.S.C. §321(g)(2).

Evidence introduced at trial indicated that Jamieson-McKames received shipments of encapsulated tetracycline at the

Morganford Road premises. These capsules were then emptied by Jamieson-McKames employees and later used to fill capsules which were bottled and labeled as "Cleocin." Further testimony showed that the "Cleocin" made from tetracycline was manufactured on a regular basis during 1974 and 1975.

Count VIII is based on the same bottle labeled "Cleocin" from the Wentzville pharmacy. Count VIII alleged the appellants caused the misbranding of the Cleocin under three separate sections of the Food, Drug, and Cosmetic Act. First, the drug was said to be misbranded within the meaning of 21 U.S.C. §352(a) because the statement "300 Cleocin 150 mg." appearing on the label represented the drug to contain clindamycin hydrochloride when it contained tetracycline. Misbranding under §352(a) requires only that the label be false or misleading. Second, the Cleocin was alleged to be misbranded under 21 U.S.C. §352(j), which deems a drug misbranded "if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." Third, the "Cleocin" was said to be misbranded under 21 U.S.C. §352(l), because it purported to be the antibiotic drug clindamycin hydrochloride, but it was from a batch for which no certificate had been issued pursuant to 21 U.S.C. §357.

The record reveals the following evidence relative to count VIII. The bottle labeled Cleocin contained capsules very similar in size, shape, and color to Upjohn's Cleocin 150 mg. FDA analysis showed the capsules contained tetracycline, a yellow powder, and no clindamycin. The reencapsulating process was accomplished by Jamieson, Sr.'s supervision. These capsules were then bottled and labeled with a Pharmacare Payless Pharmacy label and held for sale at the Wentzville pharmacy.

In addition the government presented expert testimony indicating that the substitution of tetracycline for clindamycin hydrochloride would create significant health risks, including the risk of death, to patients for whom clindamycin is prescribed.[31]

Lastly, clindamycin was shown to be an antibiotic which must be certified by the FDA prior to marketing. 21 U.S.C. §357(a); 21 C.F.R. §430.4(a)(34). It was also shown that the drug in question was not certified, and that appellants did not request certification.

The evidence in the record outlined above is sufficient to sustain convictions on counts VII and VIII. The bottle of capsules that is the basis of these counts, however, was obtained through the inspection of the Wentzville site. As was discussed earlier, the issue of the legality of the Wentzville search is unresolved pending remand to the district court on the issue of consent. Thus the judgments of conviction on counts VII and VIII must be vacated, subject to reinstatement or dismissal depending on the resolution of the consent-to-inspect issue. If the government wishes to pursue these counts, and the district court finds that there was a valid consent to the inspection under §374(a), the convictions can be reinstated, subject of course to appeal. If consent is found lacking, counts VII and VIII should be dismissed.

Count IX

Count IX of the indictment charged, and the district court found, that the appellants caused the adulteration of a drug sold as "Ampicillin" in violation of 21 U.S.C. §§331(k) and §333(b).

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[31] Dr. Joseph Marr, the government's expert, testified that tetracycline and clindamycin are used to treat different types of infections. Thus, a substitution could result in ineffective therapy. Furthermore, tetracycline only arrests the growth of micro-organisms rather than killing them. Tetracycline can also cause liver degeneration in pregnant women and impair bone development in the fetus. Clindamycin, on the other hand, does not pose such dangers.

According to the indictment the drug was adulterated in two ways: (1) within the meaning of 21 U.S.C. §351(a)(2)(B), because of failure to follow current good manufacturing practice, and (2) under 21 U.S.C. §351(b), because the strength of the drug differed from the standards set forth in an official compendium.

Evidence relevant to count IX showed the following: Pursuant to an order by Jamieson, Jr., Pharmacare received a shipment of potassium penicillin G (pen G) pills from Mallinckrodt Chemical Works in Raleigh, North Carolina. Because Mallinckrodt was discontinuing sales of antibiotics, drugs like pen G were available at reduced prices. The tablets were then ground up in a coffee grinder and packed into capsules which were then placed in bottles of 1000 each and labeled "Ampicillin." These bottles were placed in the wholesale section of the pharmacy[32] and were used to fill orders for ampicillin.[33]

The evidence supports a finding of adulteration of drugs for failure to follow current good manufacturing practices during the processing and packing of the drug. 21 U.S.C. §(a)(2)(B). FDA regulations interpreting "current good manufacturing practice" require production and control procedures to include "all reasonable precautions" to assure the safety, strength, quality, and purity of the drugs produced. The evidence indicates the appellants did not meet these standards. 21 C.F.R. §211.40(a). FDA investigators specifically asked for, but were not shown, manufacturing records for ampicillin.

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[32] The "ampicillin" that is the basis of counts IX and X was seized at the Morganford Road premises.

[33] Evidence indicated that appellants processed, packed, and labeled the Pen G "ampicillin," in order to increase the market value of the drug. Mallinckrodt sold the 250 mg. pen G tablets to Jamieson, Jr., for $9.00 per thousand. Ampicillin was also available, but at a price of $60-70 per thousand. Mallinckrodt sold no ampicillin to the appellants.

The evidence also supports a charge of adulteration as defined by §351(b), because the drug's strength, quality or purity differed from the standards set forth in a recognized compendium. Both pen G and ampicillin are drugs recognized by the United States Pharmacopeia (U.S.P.), but they are different from each other and have different pharmacological effects. A product containing pen G cannot meet the standard for ampicillin; thus, the strength of the drug differed from the standard set out in the U.S.P.

The evidence on count IX is far from insufficient. Accordingly the judgments of conviction on count IX are affirmed.

Count X

Count X charges that the "ampicillin" that was the basis of count IX was also misbranded within the meaning of 21 U.S.C. §§352(a), (j), and (l), thus violating §§331(k) and 333(b). Misbranding under §352(a) occurs whenever a drug's label is false or misleading. Section 352(j) deems a drug misbranded when it is dangerous to health when used in the manner or dosage prescribed. Finally, a drug is within the proscription of §352(1) when it is composed, at least in part, of an antibiotic, and the certification or release requirements of 21 U.S.C. §357 have not been met. Section 357 requires that antibiotics be certified prior to their sale.

Evidence presented at trial showed bottles of drugs were labeled "1000 AMPICILLIN 250," a label representing them to contain ampicillin, when they actually contained pen G. Thus the drugs' labels were false and misleading under §352(a).

Testimony of an expert witness called by the government indicated that the substitution of pen G for ampicillin was dangerous to health, because the drugs have different uses and properties. Pen G and ampicillin are effective against different types of infections. Pen G can be used for Gram-positive infections but not Gram-negative ones. Ampicillin, although effective against both types, was developed specifically to treat Gram-negative infections. The substitution of pen G for ampicillin would result in ineffective treatment of Gram-negative infections. In addition, the absorption rates of the two drugs are very different, so different doses of each are required. Thus even in those instances when both drugs are generally effective, replacement of ampicillin with pen G could result in ineffective treatment. The drug was therefore dangerous to health when used in the manner and dosage prescribed. 21 U.S.C. §352(j).

Lastly, the evidence proved that pen G and ampicillin are antibiotic drugs that must be certified by the FDA prior to marketing. 21 U.S.C. §357; 21 C.F.R. §430.4(a)(1). Once an antibiotic is certified by the FDA, an expiration date is specified. The bottles of "Ampicillin" found at Morganford Road were not certified, nor had certification been requested. This lack of certification amounted to misbranding under 21 U.S.C. §352(1).

The record supports the trial court's findings under all of the above statutory provisions. The judgments of conviction on count X are affirmed.[34]

Count XI

Count XI charges, and the district court found, that the defendants caused the misbranding of Neomycin-Polymyxin eardrops under 21 U.S.C. §§352(a) and 352(1). The statement "Expiration date 8/76" appearing on the label was said to be false and misleading and thus within §352(a). The eardrops were also alleged to contain derivatives of the antibiotics neomycin and polymyxin, which are subject to certification and release requirements. 21 U.S.C. §357(a); 21 C.F.R. §§430.4(a)(16), 430.4(a)(23). The failure to meet these requirements was said to render the drugs misbranded under §352(1).

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[34] Appellants argue that Counts IX and X improperly charge two crimes based on the same conduct. For reasons similar to those discussed above with respect to Counts V and VI, we reject this argument.

The record showed the following: Neomycin-Polymyxin eardrops with hydrocortisone and disperodon are drugs. Bottles of the eardrops were shipped to Jamieson-McKames from Atlanta, Georgia, pursuant to an order of Jamieson, Jr., in September of 1974. The eardrops bore an expiration date of July 1975. During the summer of 1975 Jamieson, Jr., directed Jamieson-McKames employees to remove the labels on the eardrops and replace them with labels with an expiration date of 8/76. This operation was carried out on several occasions. The eardrops were then distributed by Pharmacare Generic and Pharmacare according to the statement on the label. A number of the bottles were shipped from Morganford Road to the Payless Pharmacy in Salem, Missouri.

The appellants, moreover, never filed a request with the FDA for certification of the eardrops with the extended expiration date. Any such change would have had to be based on stability tests, and none was conducted here.

The above evidence amply supports the trial court's findings of misbranding under §§352(a) and (1) and the ultimate violations of §§331(k) and 333(b). The judgments of conviction on count XI are affirmed.

Count I

Count I of the indictment alleged, and the district court found, that the appellants engaged in a conspiracy from January 1, 1974, to November 5, 1975, to violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§321-392. The indictment charges that the appellants, with the intent to defraud and mislead, sold and dispensed counterfeit drugs in violation of 21 U.S.C. §§331(i)(3) and 333(b), and manufactured, processed, packed, and labeled drugs in such a way that they were adulterated and misbranded in violation of 21 U.S.C. §§331(k) and 333(b). In furtherance of the conspiracy, at least one of the appellants was alleged to have committed at least one of eight overt acts listed in the indictment.

Appellants now challenge the sufficiency of the evidence supporting the conspiracy charge.

There is ample evidence in the record that the appellants collaborated in the manufacturing, processing, packaging, and labeling of drugs in violation of various provisions of the Federal Food, Drug, and Cosmetic Act. A review of the evidence presented in our discussion of counts II through XI demonstrates continuous, widespread violations of the Act, the involvement of each of the individual defendants, and the participation of the interconnecting corporate entities. For example, Morganford Road was the site of various operations of each of the four corporate defendants. Bills owed by the several retail pharmacies were forwarded to the Morganford Road address. Jamieson, Jr., was a corporate board member of all four corporations, and Jamieson, Sr., was a board member of three of the four. The district court found, and the evidence supports the finding, that Jamieson, Sr., and Jr. had complete control of the various corporate defendants and used them to suit their own purposes. Nor does the evidence paint a picture of compartmentalized corporate functions, with information available to one corporation but not available to another. The unity of action was nearly complete.

The law has long recognized that the existence of a conspiracy need not be shown by direct proof, but that the common purpose or plan can be inferred from circumstantial evidence. *Glasser* v. *United States*, 315 U.S. 60, 80 (1942). Here, the evidence is not reflective of isolated or inadvertent instances of adulteration, misbranding, and counterfeiting, but of a continuous pattern of illegal conduct. The district court's finding of an agreement to violate the Act is fully supported. Our discussion of counts II-VI and IX-XI demonstrates the existence of adequate proof of several of the overt acts charged in the indictment.[35] What emerges is an overall plan to substitute less expensive drugs for more expensive, disregarding the safety of the public and the provisions of the Act.

Civil Action for Condemnation

The civil action was brought pursuant to 21 U.S.C. §334(a)(2)(C), which authorizes condemnation of "[a]ny punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs." The various articles of equipment involved here were seized on December 19, 1975, at the Morganford Road premises and consist of the following:[36]

1). One Stokes Model 38A Dryer, Serial No. A13960;

2). One Fratelli Zanasi Encapsulating Machine, Serial No. 12134;

3). One Patterson Kelley Twin-Shell Blender, Serial No. 163902;

4). Three stainless steel coating pans;

5). One wooden coating pan;

6). One Colton 4-stage Rotary Press (Tablet);

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[35] Overt acts 2, 4, 5, and 8 relate to substantive counts already affirmed.

[36] Another piece of equipment seized, "Encapsulating Machine Unidentified as to the Manufacturer," is no longer a part of this suit. It was remitted to its lessor, Parke, Davis, on May 23, 1977. *United States* v. *All Equipment Including But Not Limited To An Encapsulating Machine Not Identified As To Manufacturer,* 475 F. Supp. 39, 40 (E.D. Mo. 1979).

7). Four sets of Punches marked "10" on one end and blank on the other end; one Punch marked "10" without the corresponding blank end; and

8). Four Dies corresponding to the four sets of Punches.

Appellant[37] now appeals the condemnation and forfeiture of the above items of equipment. We have carefully examined the evidence of record as to each item condemned, and the judgment in the civil case is affirmed. The district court's findings are not clearly erroneous (indeed, they are clearly correct), and no error of law appears.

V. Conclusion

The judgments of conviction on Counts I-VI and IX-XI are affirmed. The judgment of condemnation in the civil action is affirmed. The judgments of conviction on Counts VII and VIII are vacated, and the cause remanded for further proceedings (if desired by the United States) as to those counts, in accordance with Part II of this opinion. As a result, the total time of imprisonment is reduced from eight years to seven.

It is so ordered.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT

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[37] As claimant of the equipment, Jamieson-McKames is the only appellant in the civil appeal.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Nos. 79-1367 and 79-1708

No. 79-1367

United States of America,
Appellee,
v.
Jamieson-McKames Pharmaceuticals, Inc., et al.,
Appellants.

No. 79-1708

United States of America,
Appellee,
v.
Jamieson-McKames Pharmaceuticals, Inc.,
Appellant.

Appeals from the United States District Court
for the Eastern District of Missouri.

Order On Rehearing

Filed: August 7, 1981

Before LAY, Chief Judge, STEPHENSON and ARNOLD, Circuit Juges.

The petition of the appellants for rehearing or rehearing en banc is denied.

The petition of the United States for rehearing is denied. The petition of the United States for clarification is granted, and the opinion of this Court, filed on May 21, 1981, is amended by adding the following new paragraph after the 13th line on p. 17 of the slip opinion:

> We add a word of clarification as to the meaning of the term "consent" as we intend it in this context. We do not mean, by imposing a requirement of "consent," to require a factual determination as to whether appellants, with respect to the Wentzville site, knowingly and understandingly relinquished a known right. The question is whether appellants refused to permit entry or inspection, thereby violating 21 U.S.C. §331 (f). If they did so refuse, then FDA was obliged to obtain an administrative warrant in order to effect the inspection, and could also seek a separate criminal prosecution for the refusal itself. If appellants did not refuse to permit entry or inspection, then they "consented" to the search and seizure, as we use that term here. This formulation, while it may not answer every question that may arise with respect to searches and seizures pursuant to §374 notices of inspection, seems to us to be the most logical way to harmonize *Biswell* and *Colonnade.* As the court said in *United States* v. *Litvin, supra,* 353 F. Supp. at 1338:
>
> Therefore, as in *Colonnade,* if defendant refused entry to the Food and Drug Administration inspectors he was in violation of §331(f) and subject to one-year imprisonment and/or $1000 fine. But if defendant refused entry, the inspectors had no right to enter the storeroom, and following *Colonnade,* any evidence seized as a result of the search must be suppressed.

The opinion of this Court is further amended by striking therefrom that portion of footnote 10 on page 14 beginning with the words, "*Buf cf.*" and ending at the end of page 14, and inserting in lieu thereof the following: "*Cf. Donovan* v. *Dewey,* 49 U.S.L. Week 4748 (U.S. June 17, 1981) (No. 80-901) (mining industry held within the *Colonnade-Biswell* exception)."

Each side will bear its own costs.

It is so ordered.

A true copy.

ATTEST:

CLERK, U. S. COURT OF APPEALS, EIGHTH CIRCUIT.

APPENDIX C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 77-131 Cr (3)

United States of America,
Plaintiff,
v.
Jamieson-McKames Pharmaceuticals, Inc., et al.,
Defendants.

Order

The United States Magistrate has filed his Report and Recommendation with respect to the joint motion of the defendants to suppress evidence. After carefully examining the premises of the motion and the Magistrate's Report and Recommendation,

IT IS HEREBY ORDERED that the Report and Recommendation of the United States Magistrate be and is sustained, adopted and incorporated herein; and

IT IS FURTHER ORDERED that the joint motion of the defendants to suppress be and is denied.

/s/ John F. Nangle
United States District Judge

Dated this 7th day of September, 1977.

Report And Recommendation
Of United States Magistrate

The District Court referred the joint motion of the defendants to suppress evidence to the undersigned United States Magistrate for a report and a recommended disposition. *See* 28 U.S.C. §636(b)(1)(B).

The defendants Jamieson-McKames Pharmaceuticals, Inc.; Pharmacare Generic Drugs, Inc.; Pharmacare, Inc.; Pay-Less Pharmacy, Inc.; James C. Jamieson, Jr.; and James C. Jamieson, Sr., are charged variously with one count of conspiracy to violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§321-392, and ten substantive violations of the Act.

In their motion to suppress defendants allege that government agents unlawfully seized evidence from defendants' business premises at two locations: 3227-29 Morganford Road, St. Louis, Missouri, and 514 West Pierce, Wentzville, Missouri. On August 4, August 26, and August 30, 1977 the Court heard oral argument and received evidence upon defendants' motion. With the exception of August 4, all defendants were present and represented by counsel. On August 4 defendant Jamieson, Jr., was absent, although he was represented by counsel. On August 5 that defendant filed a written waiver of his right to be present on August 4.

On October 29, 30, 31 and November 3, 1975 federal and state agents inspected defendants' premises at 3227-29 Morganford Road, St. Louis, Missouri. Samples of drugs were taken, documents were photocopied, quantities of drugs were embargoed, and machinery was seized. FDA inspectors, Missouri state inspectors, and a deputy United States Marshal executed these warrants by means of the inspection and seizures: On October 29, 1975 a Warrant for Arrest of Property was issued by this Court in Civil Cause No. 75-985 C (3) ordering the United States Marshal to seize certain drugs at the Morganford premises. On October 23, 1975 the United States Magistrate issued a Warrant for Inspection under the Federal Food, Drug, and Cosmetic Act against the same premises. Prior to the inspection the Circuit Court of the City of St. Louis issued a Warrant for Inspection and Seizure under Chapter 195, Revised Statutes of Missouri, and a Warrant for Inspection under Chapter 196. On November 3, 1975 an Amended Warrant for Arrest of Property was issued by this Court. Also at the commencement of the inspection an FDA inspector issued an administrative Notice of Inspection.

On October 29 and 30, 1975 FDA and Missouri state agents inspected defendants' premises at 714 West Pierce Road, Wentzville, Missouri, and certain items were seized. The FDA inspection was predicated upon an FDA administrative Notice of Inspection under 21 U.S.C. §374(a).

The grounds of the defendants' instant motion are that:

(1) the Warrant for Inspection issued by the United States Magistrate was deficient in that

(a) it lacked probable cause;

(b) it failed to specify the corporate entity being subjected to the search;

(c) it was not authorized by 21 U.S.C. §374 since the premises was a pharmacy;

(d) it was executed after the authorized time of day;

(e) the scope of the inspection was too great;

(f) the return of the warrant failed to indicate the specific locations within the premises from which the items were seized;

(2) the purpose of the civil proceedings for inspection warrants was to obtain evidence not otherwise available;

(3) defendant Jamieson, Jr., was subpoenaed to appear before the federal grand jury and was required to produce documents without lawful authority; and

(4) the two state warrants were insufficient as to the affidavits in support, in that they were issued together, and in that the subject premises were that of a drug manufacturer, not of a pharmacy.

At the evidentiary hearing defendants offered the testimony of Wilma I. Ele, a United States Food and Drug Administration ("FDA") investigator, and Richard D. Turner, an FDA Supervisory Investigator. The Government offered the testimony of Mrs. Laura Anglin, Ms. Caroline Homa, and Larry Malof. The defendants and the Government referred in their memoranda to the orders, warrants, and affidavits filed in this Court and in the Circuit Court of the City of St. Louis. Copies of these documents were provided the Court and the undersigned has taken these documents into consideration.

Miss Ele testified as follows: She participated in the October inspection of the Morganford premises. The inspection commenced at approximately 10:00 A.M. on October 29. The inspection that day ended at 6:00 P.M. Participating in the inspection were FDA agents, Missouri state agents, and a Deputy United States Marshal who executed the warrant for the arrest of property. The federal agents presented the Federal Warrant for Inspection to defendant Jamieson, Sr. at the commencement of the inspection. Before October 29 the FDA agents were aware that several corporations operated their business on those premises: Pharmacare Generic Drugs, Inc.; Pay Less Pharmacy Inc.; and Pharmacare, Inc. The building on these premises contained several rooms, generally as described in Defendant's Exhibit A. The inspection was carried out in all of the rooms. An attempt was made to determine which portions of the building were operated by which corporations.

Observation by the FDA agents indicated that the separate rooms of the building were shared by the corporations in their operations and that their storage areas overlapped. The FDA Notice of Inspection for the Morganford premises was directed only to Jamieson-McKames Pharmaceuticals, Inc., doing business as Pharmacare Payless Pharmacy. The agents inquired as to the firm's usual operating hours, for the purpose of determining the hours of the inspection. On November 3, when the amended warrant for arrest of property was presented at 4:30 P.M., defendant Jamieson, Jr. stated he would like the agents to finish the inspection that evening rather than return another day. During the inspection many photos, samples of drugs, and photocopies of records were taken. Mr. Jamieson, Sr., accepted the Notice of Inspection and the Warrant for Inspection, and told the agents to proceed with their inspection. In the Wholesale Section of Pharmacy there were observed large quantities of drugs and raw materials. Also in this area were shelves relating to the Retail Section of Pharmacy. In the Liquids Manufacturing Area and in the Packaging Materials area items were seized which appeared to be used in the Retail Section of Pharmacy. Some items seized from the Packaging Materials areas were labeled Jamieson-McKames Pharmaceuticals, Inc. The Deputy United States Marshal seized items, at FDA direction, in execution of the Warrant for Seizure of Property. The focus of the investigation was on apparent violations of the Federal Food, Drug, and Cosmetics Act. She was told by other FDA personnel that defendant Jamieson, Jr. protested the inspection. In instances where samples were taken by FDA agents, receipts for the samples were issued to defendant Jamieson, Jr., on the first day, and thereafter to defendant Jamieson, Sr.

Richard D. Turner testified as follows: He participated, with another FDA inspector and Missouri state agents, in the inspection of the Wentzville premises. An administrative Notice of Inspection was issued to Larry Malof, a pharmacist on the premises. No court authorization was issued for the inspection.

Malof described himself as the manager of the premises. Malof told the inspectors that there were three officers of Pay Less Pharmacy, Inc.: defendant Jamieson, Sr., defendant Jamieson, Jr., and Gerald Igel. Malof also stated that the firm operated as a subsidiary of Pharmacare, Inc. On October 29, 1975 the inspection extended from 10:00 A.M. to 6:00 P.M.; on October 30 from 9:30 A.M. to 4:00 P.M. Photos of the premises were made and documents were photocopied. The inspection focused on certain drugs previously complained about, antibiotics, drugs manufactured by Jamieson-McKames, "lookalike" drugs, and anything that appeared to be a violation of the Act. Samples of 48 drugs were taken. State inspectors embargoed drugs. These premises were comprised of one work area and a restroom. Prior to this inspection he had learned that certain drugs were sold there in violation of the Act. After the inspectors arrived Malof told them to proceed with the inspection. Observed on the premises were documents captioned "Pharmacare, Inc.", showing receipt of drugs. Malof identified Pharmacare, Inc., with Jamieson-McKames which was located at 3227-29 Morganford. Malof never objected to the taking of samples or the copying of documents.

Mrs. Laura Anglin, sister-in-law of defendant Jamieson, Jr., testified: In 1976 she became employed by Pharmacare Generic Drugs, Inc., at 3227-29 Morganford. In December 1974 she was hired by Jamieson-McKames Pharmaceuticals, Inc. at the same address. Both corporations operate from that address. In her employment duties for both corporations she filled the drug orders of five pharmacies, including the pharmacy operated from the Wentzville premises. These pharmacies were owned by defendant Jamieson, Jr., and defendant Jamieson, Sr. Prior to October 1975, when ordering drugs, the pharmacist at each pharmacy called in the drug orders. Mrs. Anglin, in receiving the order, would fili out an order form captioned "Pharmacare." Ultimately one copy of the form would be sent to the ordering pharmacy with the order. Occasonally defendant Jamieson, Sr., would hand deliver the drugs for the pharmacy in Hillsboro, near his home. The drugs shipped to these pharmacies included drugs manufactured and packed at 3227-29 Morganford. As an employee she handled bank account check books for each of the pharmacies and for Jamieson-McKames Pharmaceuticals, Inc., and Pharmacare Generic Drugs, Inc. Both defendant Jamieson, Jr., and defendant Jamieson, Sr., sign checks on these accounts. All bill paying through these accounts has been done at the Morganford address since December 1975 at the direction of defendant Jamieson, Jr. Her employment duties with Pharmacare Generic Drugs, Inc., did not differ substantially from those with Jamieson-McKames Pharmaceuticals, Inc. Lately she has become aware that each pharmacy was owned by a different corporation, as indicated by the names on the check book accounts. The retail pharmacy at the front of 3227-29 Morganford is unrelated to the other areas of the premises, including the manufacturing and packaging areas. Referring to Defendants Exhibit A, drug orders for pharmacies were received over telephones located in the Retail Section of the Pharmacy and the General Office Space. The order form is then laid on a table in the Wholesale Section of the Pharmacy. The filled order boxes are placed in the Label Storage and Shipping Operations room and shipped from the Loading Dock. On October 29 she saw defendant Jamieson, Jr., tell Ms. Ele to get out of the premises.

Ms. Caroline Homa testified: In May 1975 she was hired by Jamieson-McKames Pharmaceuticals, Inc., to perform drug packaging and cleaning duties. Between May and October 1975 she also took drug orders from the same pharmacies that Mrs. Anglin testified to. She filled orders on an order form captioned "Pharmacare." During July 1975 she worked on the business checking accounts. The checks were signed by either defendant Jamieson, Jr. or Sr. During her employment at 3227 Morganford, she worked in the Wholesale Section of Pharmacy, Label Storate and Shipping Operations room, General Office Space room, and the Packaging Materials area. In the Retail Section of Pharmacy retail customers had prescriptions filled and did not enter other parts of the building. Only pharmacies related to the defendants had their orders filled at 3227 Morganford, with the exception of one operated by Max Creek. Doctors' orders for drugs were filled at 3227 Morganford. She was present during the October 1975 inspection.

Larry Malof testified: He is a registered Missouri pharmacist. In April 1974 he was hired at 512 W. Pierce, Wentzville, Missouri, named the Pay-Less Pharmacy. He was hired by defendant Jamieson, Jr. He ordered his drugs from an unrelated wholesaler in St. Louis and also from Pharmacare Generic at 3227-29 Morganford. All finances for the Wentzville facility were handled through the office at 3227-29 Morganford. He did, however, make bank deposits for his pharmacy and send the deposit slip to the Morganford office.

Defendants and the Government stipulated that Missouri state agents seized no items during the two inspections. However, they embargoed materials. The Government does not intend to use as evidence any item seized by the state agents.

The application for the Federal Inspection Warrant issued by the United States Magistrate under 21 U.S.C. §374 was signed under oath by Steven G. Kendall, a Federal Food and Drug Investigator. It specifically identified the premises to be searched: 3227 Morganford Road, St. Louis, Missouri; it identified the operator of the premises: Jamieson-McKames Pharmaceuticals, Inc., also doing business as Pharmacare Pharmacy, Inc. The application recited the receipt of drugs and the repackaging of these drugs. It recited that certain drugs were manufactured and mislabeled, that FDA approval is required before these new drugs can be marketed, and that FDA approval has not been granted. The source of this information was not set out, although Kendall swore that the facts were true to his knowledge and belief.

To determine whether the application supplied probable cause the Court must weigh the need for the inspection in terms of the reasonable goals of the Act against the resultant invasion. *Camara* v. *Municipal Court*, 387 U.S. 523, 534-537 (1967). "If a valid public interest justifies the intrusion contemplated, then there is probable cause to issue a suitably restricted search warrant." *Id.* at 539. The public interests underlying the Federal Food, Drug, and Cosmetic Act have been described as keeping interstate channels free from deleterious, adulterated and misbranded articles so that public health and safety may be advanced, *see United States* v. *Walsh,* 331 U.S. 432 (1947), and the protection of the public from products not proven to be safe and effective for their alleged uses and the safeguarding of public health by enforcement of certain standards of purity. *United States* v. *Diapulse Corporation of America,* 457 F.2d 25, 27-28 (2nd Cir. 1972). Kendall's application, setting out his official position, the purposes of the inspection, the scope of the inspection, and facts indicating the likelihood of Act violations supplied probable cause for the warrant.

The application and the warrant sufficiently specified the corporate entity to be subjected to the inspection.

A pharmacy is subject to inspection under the first sentence of 21 U.S.C. §374(a) as an "establishment in which . . . drugs . . . are manufactured, processed, packed or held, for introduction into interstate commerce or after such introduction . . . ." 21 U.S.C. §374(a). *See United States* v. *Herold,* 136 F.Supp. 15, 16 (E.D.N.Y. 1955). The second sentence of §374(a) subjects pharmacies to inspection which manufacture, prepare or process drugs for sale other than in its regular retail operation. During the hearing the defendants and the Government offered evidence which treated the corporate identities of the operations on the Morganford and the Wentzville premises. The evidence clearly indicated that, regarding the Morganford premises, the purposes of the rooms and work areas, and the duties of the employees, indicated substantial commingling of the businesses of the defendants. The inspection on those premises was not unlawful because the execution of the court orders did not recognize and acceed to the boundaries of the corporate entities as understood by the defendants. *United States* v. *Del Campo Baking Mfg. Co.*, 345 F.Supp. 1371, 1378 (D.Del. 1972).

The warrant authorized the inspection "at reasonable times during ordinary business hours." The evidence adduced at the hearing indicated that the inspection took place between the hours of 9:30 A.M. and 6:00 P.M. on October 30, between 9:00 A.M. and 6:00 P.M. on October 31, and between 9:00 A.M. and 11:00 P.M. on November 3. On November 5 the FDA agents returned to the premises for approximately one hour to discuss the inspector's findings with the management.

Defendants assert in their memorandum of law filed August 12, 1977 that the normal business hours of the operation were between 9:30 A.M. and 4:00 P.M. FDA Inspector Ele testified that defendant Jamieson, Jr., gave permission to the agents to continue their inspection after 4:00 P.M. on November 3. The continuation of the inspection after 4:00 P.M. on October 30 and 31 was still within ordinary business hours, terminating at 6:00 P.M. *Cf., United States* v. *Joseph,* 278 F.2d 504, 505 (3rd Cir. 1960), *cert. denied,* 364 U.S. 823 (1960).

The scope of the inspection was authorized by the warrant to include all pertinent equipment, finished and unfinished materials, containers, labeling and all records subject to inspection. Seizure of these items was authorized by 21 U.S.C. §374(a). Evidence adduced at the hearing indicated that the agents also seized many samples of drugs during the inspection. Section 374(a) empowered the agents to seize drug samples. *United States* v. *El Rancho Adolphus Products, Inc.,* 140 F.Supp. 645, 651 (M.D.Pa. 1956), *aff'd* 243 F.2d 367 (3rd Cir. 1957), *cert. denied,* 353 U.S. 976 (1957).

The return of the federal warrant, filed by Investigator Kendall, incorporated the return of the Deputy United States Marshal filed in Civil Cause No. 75-985 C (3). This return listed the amounts of the drugs seized, the names of the products, and the lot numbers. Defendants assert that the return fails to indicate the locations within 3227 Morganford from which the items were seized. This failure to specify the locations of each item seized does not detract from the sufficiency of the warrant and its purpose of providing a list of items seized from the premises set forth in the warrant.

Defendants argue that the two Missouri state warrants were not based upon sufficient affidavits and were improperly issued together; and that the items were improperly seized under these warrants because the items were possessed by a manufacturer, not a pharmacy. The undersigned has studied the applications of Ernie Sjoblom, an Agent of the Missouri Division of Health, and finds that the subject state warrants were properly issued together and were founded upon probable cause set forth in the Sjoblom applications. Furthermore, the United States indicates that the drugs seized by the state agents from the premises at 3227-29 Morganford have been destroyed subsequent to state proceedings. None of the seized drugs will be used as evidence in this federal prosecution.

The Government represents, and the defendants have not subsequently controverted, that the basis for the inspection at the defendants' facility in Wentzville, Missouri, was 21 U.S.C. §374 for the FDA agents and §§195.030(7) and 196.055, R.S.Mo., for the state agents. The FDA agents presented an administrative Notice of Inspection to Larry Malof, the pharmacist in charge of the premises, when the inspection began, as required by §374. Defendants argue that §374 does not authorize the inspection of pharmacies. As stated above pharmacies are subject to inspection under the first sentence of §374(a). The premises of a pharmacy are subject to inspection under the second sentence of §374(a) if the pharmacy engages in wholesale drug operations. 21 U.S.C. §374(a)(1). As stated above, the defendants, through commingled corporate entities operated retail and wholesale businesses. Since the Wentzville premises were run by an entity which was involved in wholesale operations on the Morganford premises, the Wentzville premises were subject to the second sentence of §374(a).

Furthermore, the warrantless nature of the inspection did not violate defendants' constitutional rights as alleged. *Cf., United States* v. *Biswell,* 406 U.S. 311 (1972).

The record disclosed ample grounds for the federal and state civil inspection and seizure proceedings. Defendants offered no evidence to counter the Government's argument that the appearance of defendant Jamieson, Jr., before the grand jury was lawful. *Curcio* v. *United States,* 354 U.S. 118, 125 (1957).

Recommendation

Finding no merit in defendants' grounds for relief, it is the recommendation of the undersigned United States Magistrate that the motion of the defendants to suppress evidence be denied.

Respectfully submitted,

/s/ David D. Noce
United States Magistrate

Dated this 6th day of September, 1977.

APPENDIX D

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 77 - 131 CR (3)

United States of America,
Plaintiff,

v.

Jamieson-McKames Pharmaceutical, Inc., et al.,
Defendants.

Memorandum

This matter is before the Court following a trial to the Court sitting without a jury. Defendants are charged with violations of 21 U.S.C. §333 and 18 U.S.C. §371. Although not requested to do so, the Court makes the following findings of fact, Rule 23, Federal Rules of Criminal Procedure:

1) Defendant Jamieson-McKames Pharmaceutical, Inc. is a corporation organized and existing pursuant to the laws of the state of Missouri. During the times relevant herein, said defendant was engaged in the business of buying, manufacturing, packaging, labeling, distributing and selling drugs. Said defendant sold drugs directly to doctors, clinics and pharmacies, through Pharmacare, Inc. and Payless Pharmacy, Inc. At all times relevant herein, the activities of defendant Jamieson-McKames were carried out by James C. Jamieson, Sr.; James C. Jamieson, Jr.; James C. Jamieson, III, a part-time employee; and approximately five other employees.

2) Defendant Pharmacare, Inc. is a corporation organized and existing pursuant to the laws of the state of Missouri,

engaged in the business of manufacturing, purchasing, packaging, labeling, distributing and selling drugs, as well as operating pharmacies and drug stores. Pharmacare operated three retail pharmacies. All bills for said pharmacies were forwarded to Pharmacare's principal place of business, which was in the same location as Jamieson-McKames' principal place of business. Pharmacare also operated two pharmacies in doctors' offices. One, in the office of a Dr. Vermilyea, was the result of an agreement entered into by said doctor, and Jamieson, Jr. and Jamieson-McKames. The employee who ran the pharmacy was paid on the Pharmacare account or the Jamieson-McKames account. The second pharmacy, in the office of Dr. Salit and Dr. Eckert, was opened after an agreement was reached between the doctors and Jamieson-McKames. Jamieson-McKames stocked the pharmacy, hired the employee and paid the bills. Jamieson-McKames also shared the profits with the doctors. Employees of Jamieson-McKames accepted orders on behalf of Pharmacare. Drugs were frequently labeled with Pharmacare Payless Pharmacy labels whether the drug was for a Payless or Pharmacare pharmacy, or for a pharmacy unconnected with any of the defendants herein.

3) Defendant Payless Pharmacy, Inc. is a corporation organized and existing pursuant to the laws of the state of Missouri, engaged in the business of manufacturing, packaging, labeling, distributing and selling drugs. Said defendant also operated two retail pharmacies. Bills for the pharmacies operated by Payless were forwarded to the principal place of business of Payless, at the same location as the principal place of business of Jamieson-McKames. A Jamieson-McKames employee would fill out the checks for payment; said checks were then signed by Jamieson, Sr., and Jamieson, Jr.

4) Defendant Pharmacare Generic Drugs, Inc. is a corporation organized and existing pursuant to the laws of the state of Missouri, engaged in the business of purchasing, manufacturing, packaging, labeling, distributing and selling drugs. Said corporate defendant had no employees.

5) Defendant James C. Jamieson, Sr. was, at all times relevant herein, a member of the Board of Directors, and President and Treasurer of Jamieson-McKames Pharmaceutical, Inc.; a member of the Board of Directors, and Vice-President and Secretary of Pharmacare Generic Drugs, Inc.; and during 1975, a member of the Board of Directors of Pharmacare, Inc. Said defendant had been observed engaged in certain manufacturing operations; he was seen operating an encapsulating machine, a dryer, and a coating machine.

6) Defendant James C. Jamieson, Jr. was, at all times relevant herein, a member of the Board of Directors, and Vice-President and Secretary of Jamieson-McKames Pharmaceutical, Inc.; a member of the Board of Directors, and President and Treasurer of Pharmacare Generic Drugs, Inc.; a member of the Board of Directors, and President and Treasurer of Pharmacare, Inc.; and a member of the Board of Directors, and President and Treasurer of Payless Pharmacy, Inc.

7) The evidence revealed that these individual defendants had complete control of the various corporate defendants. The individual defendants used these corporations to suit their own purposes and there is little consistency in the roles of each corporation.

8) "Motrin" is the trademark of the Upjohn Company which has used said trademark for the drug ibuprofen since 1970. The Upjohn Company, a licensee of the patent holder, has not authorized any of the defendants herein to manufacture ibuprofen. The evidence failed to establish that defendants had been licensed or authorized by any other company to manufacture ibuprofen. The demand for Motrin far exceeded the supply availble in 1974 and 1975. In June, 1975, defendant Jamieson, Jr. ordered magnesium salicylate tablets from C. M. Bundy Company of Cincinnati, Ohio. In accordance with said defendant's request, the tablets were manufactured with a Motrin tablet as the standard of appearance. Defendant Jamieson-

McKames received, and paid for, the shipment. Thereafter, Dr. Zack A. Barnes, located in King City, Missouri, ordered 1000 Motrin tablets from defendant Jamieson-McKames. The bottle of Motrin received as a result of this order was labeled with a Pharmacare Payless Pharmacy label, identifying the contents as Motrin. The use of the name Motrin was without authorization of The Upjohn Company. The tablets did not contain ibuprofen. These tablets were also sold as Motrin in the pharmacy operated by Pharmacare, Inc. in the office of Dr. Salit and Dr. Eckert. They were also sold in a pharmacy operated by defendant Payless. In selling these tablets, improperly labeled as Motrin, defendants Jamieson, Sr., Jamieson, Jr., Jamieson-McKames Pharmaceutical, Inc., Payless Pharmacy, Inc. and Pharmacare, Inc. acted with intent to defraud and mislead Dr. Barnes and others as to the true content of the tablets. By labeling the bottle as Motrin, said defendants intentionally misrepresented that the tablets were the products of The Upjohn Company and contained ibuprofen; neither representation was true. The evidence established that the tablets contained magnesium salicylate.

9) "Valium" is the trademark of Hoffmann-LaRoche for the drug, diazepam. Hoffmann-LaRoche holds the patent for said drug. Hoffmann-LaRoche has never authorized any of defendants herein to use its trademark Valium or to manufacture diazepam. Defendant Jamieson-McKames received a shipment of bulk diazepam from Gyma Laboratories. Defendant Pharmacare, Inc. sold the diazepam, and held the same for sale, in bottles labeled "Valium", on the labels of Pharmacare Payless Pharmacy, Inc. In addition, defendant Jamieson-McKames sold the same to pharmacies unconnected with any of defendants herein. The drug resembled Hoffmann-LaRoche's Valium in size, shape and color. The diszepam sold by these defendants bore the trademark Valium on its label and thus falsely purported and was represented to be the product of Hoffmann-LaRoche, Inc. Said defendants held these tablets for sale in

their mislabeled state with intent to defraud and mislead. Although the diazepam tablets were regularly manufactured by defendant Jamieson, Sr. at the facilities of Jamieson-McKames, no manufacturing records were kept. Defendants were well aware that this product would be used to fill prescriptions which specified Valium.

10) Potassium phenoxymethyl pencillin [pen V] and potassium pencillin G [pen G] are both drugs; they are, however, different from each other. In January, 1975, pursuant to an order of defendant Pharmacare Generic, a shipment of pen V, with an expiration date of August, 1975, was sent from New Jersey to Missouri. The receipt of said shipment was logged by employees of Jamieson-McKames. During the period from January to November, 1975, bottles of said drug were relabeled to reflect that the bottles contained pen G, marketed by defendant Pharmacare Generic. Since the bottles contained no pen G, the strength of the drug contained therein differed from that which it purported to possess. Defendants Jamieson, Sr. and Jamieson, Jr. failed to maintain adequate controls and records of the receipt, sampling, testing and examination, repacking, labeling and distribution of said drug, despite the fact that both individual defendants were well aware of the requirements of good manufacturing practices. Not only were the bottles labeled pen G, but the expiration date stated thereon was July, 1977. Thus, the labels represented that the bottles contained a drug, which they did not, and that the drug had an expiration date almost two years after the true expiration date of the actual drug contained therein. Additionally, the drug contained in the bottles was from a batch with respect to which no certificate or release was in effect, and the drug was not exempted from such requirements. The relabeling was done at the direction of defendant Jamieson, Jr.

11) Clindamycin hydrochloride and tetracyline hydrochloride are both antibiotic drugs. They are different drugs. "Cleocin" is the trademark of The Upjohn Company for

the drug clindamycin hydrochloride. Said company has not authorized any of the defendants to use its trademark Cleocin. The Upjohn Company also holds the patent for clindamycin; it has not authorized defendants to manufacture said substance. In June, 1975, a shipment of tetracycline hydrochloride was shipped from New Jersey to St. Louis, Missouri. In September, 1975, defendant Jamieson-McKames shipped a bottle to a Payless Pharmacy, under the label of Pharmacare Payless Pharmacy. Said label stated that the bottle contained Cleocin; in fact, it contained tetracycline hydrochloride. The capsules contained in the bottle were almost the same size, shape and color as Cleocin. From the period between June, 1975 and September, 1975, these defendants, along with Jamieson, Sr., and Jamieson, Jr., with intent to defraud and mislead, repacked the tetracycline hydrochloride from its original capsules into different capsules and placed the same into bottles labeled Cleocin. These bottles were held for sale by said defendants. The labeling was clearly false and misleading since it represented that the capsules contained Cleocin, whose active ingredient is clindamycin hydrochloride, when, in fact, the capsules contained only tetracycline hydrochloride. These actions by defendants were dangerous to the health since the use of tetracycline hydrochloride would not be effective when clindamycin hydrochloride was the drug of choice. Additionally, the side effects and contraindications of each drug are different. Further, the drug was from a batch with respect to which no certificate or release was in effect and the drug was not exempted by regulation. Required manufacturing records were not kept.

12) Potassium pencillin G tablets [pen G] is a drug within the meaning of 21 U.S.C. §321(g)(1). Ampicillin is also a drug within the meaning of said statute but is not the same drug as pen G. In September, 1975, pursuant to an order of defendant Jamieson, Jr., Pharmacare, Inc. received a shipment of pen G from Mallinckrodt Chemical Works in Raleigh, North Carolina. These tablets were processed and packaged into cap-

sules which were then placed into bottles and labeled as ampicillin on the labels of Pharmacare Payless Pharmacy. Although labeled as ampicillin, the strength of the capsules did not comply with the standards set forth in the United States Pharmacopeia, since the capsules contained no ampicillin whatsoever. In addition, adequate controls and records on each significant step of the manufacture, processing, packing, labeling, testing, controlling and distribution of the drug were not maintained. The labeling of the drug as ampicillin was false and misleading since the capsules contained no ampicillin. The capsules were dangerous to the health in those instances where ampicillin was the drug of choice and pen G would not be effective. No certificate or release was in effect with respect to such drug, nor was the drug exempted by regulation. Defendants Jamieson, Sr., Jamieson, Jr., Jamieson-McKames, Pharmacare, Inc., and Payless Pharmacy, Inc. caused the substitution of pen G for ampicillin with intent to defraud and mislead.

13) Neomycin-Polymyxin eardrops with hydrocortisone and diperodon is a drug within the meaning of the law. Bottles of said eardrops were shipped to Jamieson-McKames from Atlanta, Georgia, pursuant to an order of Jamieson, Jr., in September, 1974. The eardrops contained an expiration date of July, 1975. From the period of September, 1974 to November, 1975, defendant Jamieson, Jr. caused said bottles, with intent to defraud and mislead, to be relabeled to reflect an expiration date of August, 1976. Said labeling was false since it represented that the eardrops had an approved expiration date of August, 1976 when, in fact, the approved expiration date was July, 1975. The drug was from a batch with respect to which no certificate or release was in effect and said drug was not exempted by regulation. The relabeled eardrops were distributed by defendants Pharmacare Generic and Pharmacare, Inc. They were held for sale by defendant Payless.

14) The evidence established that all defendants, since 1974, have conspired to engage in numerous violations of the law with the intent to defraud and mislead. Said defendants have mislabeled drugs, both as to their content and their expiration date. They have failed to comply with good manufacturing practices, although the individual defendants had knowledge of the same. Through their failure to keep records, defendants attempted to conceal their activities. The individual defendants utilized the corporate defendants in order to achieve their goals. Said corporate defendants were involved in the manufacture, distribution and/or sale of such drugs. Defendant Jamieson, Jr. caused the incorporation of Payless Pharmacy, Inc. in February, 1974. In June, 1975, Jamieson, Jr., on behalf of Jamieson-McKames Pharmaceutical, Inc. purchased magnesium salicylate tablets from the C. M. Bundy Company in Cincinnati, Ohio; said tablets were later bottled, labeled and sold as Motrin. In September, 1975, employees of Jamieson-McKames, acting at the direction of the individual defendants, labeled bottles of tetracycline hydrochloride as Cleocin, using Pharmacare Payless Pharmacy, Inc. labels. Employees of Jamieson-McKames, at the direction of Jamieson, Jr., relabeled eardrops improperly, extending the expiration date. The individual defendants engaged in a vast plan to substitute less expensive drugs for more expensive ones. Contrary to defendants' assertions, these actions were not taken in a sincere desire to save money for patients, but instead were the result of defendants' desire to reap profits. There can be no claim that defendants had a patient's interests in mind when said defendants sold drugs past their expiration date or substituted one drug for another.

Defendants have raised a number of evidentiary issues. The first two issues raised concern the propriety of searches conducted at two of defendants' business locations. The validity of these searches were raised by pre-trial motions to suppress. Following a hearing before a United States Magistrate, it was recommended that the motions to suppress be denied. This Court adopted said recommendation. The Court adheres to its ruling.

Defendants also challenge the validity of an inspection of the pharmacy operated in the offices of Dr. Salit and Dr. Eckert. Dr. Eckert granted permission for the inspection, although Dr. Salit owned the building. Defendants contend that the search was improper because it was defendant Jamieson-McKames who owned and operated the pharmacy, stocked the same, owned the merchandise therein, hired the employees, rented the space from Dr. Salit, and furnished the stock and fixtures. At the outset, the Court notes that defendants had ceased their operations at that pharmacy at the time of the inspection; thus, it would appear that defendants have no standing to challenge the same. *Cf., Mullins* v. *United States,* 487 F.2d 581 (8th Cir. 1973). Moreover, under the circumstances herein, the Court concludes that Dr. Eckert could consent to the search. See *United States* v. *Matlock,* 415 U.S. 164, 171 (1974) in which the court held that valid permission to search could be obtained "from a third party who possessed common authority over or other sufficient relationship to the premises ... sought to be inspected".

Defendants also contest the admissibility of photographs taken by inspectors of the Food and Drug Administration during the course of inspection. Defendants contend that such photographs are not authorized by 21 U.S.C. §374 but concede that such authority has been recognized in *United States* v. *Acri Wholesale Grocery Company,* 409 F.Supp. 529 (S.D. Iowa 1976). Defendants contend, however, that the photographs are not a true and accurate depiction of the premises, because materials were moved during the inspection, and thus should not have been admitted. It is not disputed that some of the photographs do not depict the exact conditions of the premises. The Court, however, fails to see any error in admitting the same for the value that they might have in aiding the Court in its understanding of the events herein. Defendants have fully explained the changed conditions which the photographs represent.

Lastly, defendants seek to exclude statements made by defendants Jamieson. Contrary to defendants' assertion, *Bruton* v. *United States,* 391 U.S. 123 (1968) is not offended by the introduction of the statements herein. Moreover, the requirements of *Miranda* v. *Arizona,* 384 U.S. 436 (1966) were not applicable since the evidence failed to establish that defendants Jamieson were in a custodial situation, subject to arrest. *Beckwith* v. *United States,* 425 U.S. 341 (1976). The parties herein agree that in order to establish a violation of 18 U.S.C. §371, the government must prove, beyond a reasonable doubt, (1) that the conspiracy was willfully formed and was in existence at or about the time alleged; (2) that the accused willfully became a member of the same; (3) that one of the conspirators thereafter knowingly committed at least one of the overt acts charged in the indictment at or about the time and place alleged; and (4) that the overt act was knowingly done in furtherance of some object or purpose of the conspiracy.

Defendants assert that there can be no finding of a conspiracy because the defendants involved herein are all corporations and their officers. The law is clear that a corporation and its officers can not conspire. Defendants refer this Court to law stating that

> ... a conspiracy between two corporations cannot be formed by the acts of one person alone acting as agent for both corporations. 19 C.J.S. Corporations §1364.

See also 15A C.J.S. Conspiracy §37. In *Cape Cod Food Products* v. *National Cranberry Association,* 119 F.Supp. 900 (D.C.Mass. 1954), however, Judge Wyzanski charged a jury as follows:

> It may happen that an individual, let us say X, is an officer of X Company, and is also interested in Y Company, and

> it may happen that when X acts, he acts both for the X Company and for the Y Company, or he acts both for the X Company and on his own account. If this situation does exist, then it is possible to find a conspiracy, because he is acting in a dual role and he is, in contemplation of law, two persons.

See also *Cole* v. *University of Hartford,* 391 F.Supp. 888 (D.C.Conn. 1975), citing the above passage with approval. Accordingly, the Court rejects defendants' arguments herein under the circumstances of this case.

The evidence of conspiracy was overwhelming, as reflected by the findings of this Court. Accordingly, the Court finds that the government proved beyond a reasonable doubt that defendants herein conspired to violate 21 U.S.C. §§331 and 333, in violation of 18 U.S.C. §371.

Having thus conspired, each defendant is liable for any substantive crimes committed by co-conspirators, as long as such substantive offense was committed in furtherance of the conspiracy, within the scope of the conspiracy, or as part of a plan which could "reasonably [be] foreseen as a necessary or natural consequence" of the conspiracy. *Pinkerton* v. *United States,* 328 U.S. 640, 647-48 (1946); see also *United States* v. *Kaplan,* 554 F.2d 958, 965 (9th Cir. 1977), Clearly, the substantive crimes charged herein were in furtherance, and within the scope, of the conspiracy.

The Court has carefully reviewed the factual and legal arguments presented by defendants herein, and rejects the same. The credible evidence clearly establishes that defendants are guilty, beyond a reasonable doubt, of each substantive count charged herein.

/s/ John F. Nangle
United States District Judge

Dated: March 29, 1979.

APPENDIX E

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 75-1150 C (3)

United States
of America,
Plaintiff,

vs.

All Equipment Including,
But Not Limited To, An
Encapsulating Machine,
etc., et al.,
Defendants.

Order

Pursuant to the memorandum filed this date, and in accordance with the provisions of 21 U.S.C. §334(d),

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that all defendant equipment is condemned and forfeited.

IT IS FURTHER ORDERED, ADJUDGED, and DECREED that the claim of Jamieson-McKames Pharmaceutical, Inc. be and is denied.

IT IS FURTHER ORDERED that the United States Marshal shall take steps pursuant to 21 U.S.C. §334(d)(1) to sell defendant equipment to persons unconnected and unrelated to any of the defendants in *United States* v. *Jamieson-McKames Pharmaceuticals, Inc.*, No. 77-131 CR (3), and to pay the proceeds of such sale, less the legal costs and charges, to the Treasury of the United States.

/s/ John F. Nangle
United States District Judge

Dated: July 23, 1979.

Memorandum

This matter is before the Court for decision upon the merits. This cause was consolidated with a related criminal action, *United States* v. *Jamieson-McKames Pharmaceuticals, Inc.*, No. 77-131 CR (3). Decision therein was rendered on March 29, 1979; the defendants, including the claimant herein, were convicted of eleven counts of adulterating, misbranding and counterfeiting drugs. On April 20, 1979, following an agreement by the parties herein that no further evidence would be adduced, the parties were ordered to submit findings of fact and conclusions of law, as well as additional briefs if necessary, in support of their positions. Plaintiff having advised this Court by telephone on July 18, 1979 that it would not file a reply brief, the matter was placed under submission to the Court.

This matter was tried before the Court without a jury.

The Court having considered the pleadings, the testimony of the witnesses, the documents in evidence, and being otherwise fully advised in the premises hereby makes the following findings of fact and conclusions of law as required by Rule 52, Federal Rules of Civil Procedure:

Findings Of Fact

1. Plaintiff United States of America brought this suit in December, 1975 alleging that defendant equipment, which had been located at 3227-29 Morganford Road in St. Louis, Missouri, was used or designed for use in making counterfeit drugs. Accordingly, plaintiff sought condemnation of the same pursuant to 21 U.S.C. §334(a)(1).

2. Defendants are various articles of equipment seized on December 19, 1975 at the Morganford Road location, and presently consist of:

   a. One Stokes Model 38 A Dryer, Serial No. A73960;

b. One Fratelli Zanasi Encapsulating Machine, Serial No. 12134;

c. One Encapsulating Machine Unidentified as to Manufacturer;

d. One Patterson Kelly Twin-Shell Blender, Serial No. 163902;

e. Three Stainless Steel Coating Pans;

f. One Wooden Coating Pan;

g. One Colton 4-Stage Rotary Press (Tablet);

h. Four Sets of Punches marked "10" on One End and Blank on the Other End; One Punch Marked "10" Without the Corresponding Blank End; and

i. Four Dies Corresponding to the Four Sets of Punches.

On June 18, 1976, Parke Davis & Company filed a claim, as owner, to the "Encapsulating Machine Unidentified as to Manufacturer". Parke Davis identified Jamieson-McKames Pharmaceuticals, Inc. as the lessee of the encapsulator. On April 4, 1977, Parke Davis consented to the entry of a judgment condemning the encapsulator pursuant to 21 U.S.C. §334(a)(2). The condemnation was remitted on May 23, 1977, upon petition pursuant to 21 U.S.C. §334(d)(3), to the custody of Parke Davis. Accordingly, since May 23, 1977, "One Encapsulating Machine Unidentified as to Manufacturer" is no longer a defendant herein.

3. On January 6, 1976, Jamieson-McKames Pharmaceuticals, Inc. filed a claim and answer on behalf of all defendant equipment. In the criminal cause, *United States* v. *Jamieson-McKames Pharmaceutical, Inc.*, No. 77-131 CR (3), this Court found and so finds herein:

Defendant Jamieson-McKames Pharmaceutical, Inc. is a corporation organized and existing pursuant to the laws of the state of Missouri. During the times relevant herein, said defendant was engaged in the business of buying, manufacturing, packaging, labeling, distributing and selling drugs. Said defendant sold drugs directly to doctors, clinics and pharmacies, through Pharmacare, Inc. and Payless Pharmacy, Inc. At all times relevant herein, the activities of defendant Jamieson-McKames were carried out by James C. Jamieson, Sr.; James C. Jamieson, Jr.; James C. Jamieson, III, a part-time employee; and approximately five other employees.

4. On June 18, 1976, Lemay Bank & Trust Company filed a claim to the "Fratelli Zanasi Encapsulating Machine, Serial No. 12134", based upon a security interest therein. On January 17, 1978, said claimant was permitted to withdraw its claim because the security interest had been satisfied.

5. Defendant encapsulating machine was located in a room at the Morganford location known as the encapsulating room. It was used to fill capsules. Defendant Colton 4-Stage Rotary Tablet Press was located in a back room at Morganford and was used in the manufacture of tablets. Defendant punches and dies, made for Jamieson-McKames Pharmaceuticals, Inc. by Advance Engineering in March, 1975, were specially made for defendant Tablet Press. Defendant Stokes Model 38 A Dryer, also located at Morganford, was used to prepare granulations, after mixing, for the manufacture of tablets. Defendant Patterson Kelly Twin-Shell blender, located in a room by itself at Morganford, is designed for use in mixing granulations for tablets or capsules. The four coating pans, also located at Morganford, are designed for coating tablets. The evidence establishes, however, that the coating pans were also used to mix "powders" or "beads" even though such usage would result in inadequate mixing because of the slow rotation of the coating pans.

6. Defendant Dryer was used by claimant to dry a yellow granulation, analyzed as diazepam. This drug is the active ingredient in Valium, a trademark of the drug manufacturer, Hoffmann-LaRoche. Neither claimant nor its officers or agents were authorized to use the trademark Valium. Nevertheless, claimant sold diazepam with the trademark Valium, thus falsely purporting and representing the drug to be that of Hoffmann-LaRoche.

7. Defendant Fratelli Zanasi Encapsulating Machine was used by James C. Jamieson, Sr., a member of the Board of Directors, and President and Treasurer of claimant Jamieson-McKames Pharmaceutical, Inc. In October, 1975, empty size 4, black/green capsules were collected from the Encapsulating Machine, and a balance nearby. Chlordiazepoxide powder was collected from the Encapsulating machine as well. Hoffmann-LaRoche Librium 10 mg. is a size 4 black/green capsule containing chlordiazepoxide. The evidence established that claimant sold, as "Librium", a look-alike drug which did not contain the Hoffmann-LaRoche logo. Neither claimant nor its officers or agents were authorized to use the trademark "Librium". Also located near the Encapsulating Machine were size 4 red/white capsules. The evidence established that the Encapsulating Machine and these capsules were used to make capsules labeled "Serax" a product of Wyeth. Claimant did not have authorization to use said trademark; the capsules did not contain Serax nor did they bear the Wyeth logo. The evidence established that "Serax" was made at the Morganford location.

8. Defendant Twin-Shell Blender was used in the preparation of misbranded, adulterated and counterfeit drugs. It was the only suitable machine located at Morganford for mixing powers and granulations in the quantities produced by claimant.

9. Defendant Coating Pans were used to mix, blend, and coat the misbranded, adulterated and counterfeit drugs produced by claimant.

10. Defendants Rotary Press, Punches and Dies were also used to produce misbranded, adulterated and counterfeit drugs. Claimant distributed and sold drugs labeled as "Valium", "Diabinese", and "Zyloprim", although said products were not that of their legitimate manufacturers. Defendant punches and dies were identical to those used by Mead Johnson in the production of Vasodilan 10 mg. tablets. John Markovitch, who distributed drugs for Jamieson-McKames Pharmaceuticals, Inc., sold tablets which were labeled "Vasodilan 10" with a debossed "10" on the tablet. These were sold by the name of "Vasodilan" but were not the Mead Johnson product. Punches and dies were discovered at Morganford which corresponded to "Sudafed", manufactured and sold by claimant although neither claimant nor its officers were authorized to use said trademark. Similarly, punches and dies corresponding to "Chlorpropamide . . . Diabinese" were found although claimant had no authorization to manufacture or use the trademark of such product. All the products so manufactured by claimant resembled the legitimate manufacturer's product in size, shape, and color. Claimant sold or distributed said products as if they were products of the legitimate manufacturer.

Conclusions of Law

This Court has jurisdiction over the subject matter and the parties to this suit pursuant to 21 U.S.C. §334(a).

Claimant asserts herein only that:

1. There is no direct casual connection between the Defendant equipment and machinery and any counterfeit drug or drugs.
2. Defendant machinery and equipment was not engaged in the manufacture or production of any counterfeit drug or drugs.

3. Defendant machinery and equipment is therefore not subject to the condemnation and forfeiture.

The Court has found that all of defendant equipment and machinery was in fact used by claimant, its officers and agents, in the production of adulterated, counterfeit and misbranded drugs. By virtue of the provisions of 21 U.S.C. §334, said items are subject to, and will be, condemned and forfeited.

Appropriate orders to the United States Marshal will issue.

/s/ John F. Nangle
United States District Judge

Dated: July 23, 1979.

APPENDIX F

Judgment

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT
September Term, 1980

79-1367

United States of America,
Appellee,
v.
Jamieson-McKames Pharmaceuticals, Inc., Pharmacare Generic Drugs, Inc., Pharmacare, Inc., Payless Pharmacy Inc., James C. Jamieson, Sr., James C. Jamieson, Jr.,
Appellants.

Appeal from the United States District Court for the Eastern District of Missouri.

This cause was heard on a designated record from the United States District Court for the Eastern District of Missouri and was argued by counsel.

After consideration it is now ordered and adjudged that the judgments of conviction on Counts I-VI and IX-XI are affirmed. The judgments of conviction on Counts VII and VIII are vacated, and the cause remanded for further proceedings (if desired by the United States) as to those counts, in accordance with Part II of this opinion. As a result, the total time of imprisonment is reduced from eight years to seven.

May 21, 1981

A True Copy:

ATTEST: /s/ Robert D. St. Vrain

Clerk, U.S. Court of Appeals, Eighth Circuit

APPENDIX G

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

IN THE MATTER OF ESTABLISHMENT INSPECTION OF
JAMIESON-McKAMES PHARMACEUTICALS, INC.,
ALSO DOING BUSINESS AS PHARMACARE
PHARMACY, INC., 3227 MORGANFORD ROAD,
ST. LOUIS, MISSOURI

Application for inspection warrant under the Federal Food, Drug, and Cosmetic Act

TO THE UNITED STATES MAGISTRATE

STEVEN G. KENDALL, a duly authorized Food and Drug Investigator of the Food and Drug Administration, Department of Health, Education and Welfare, St. Louis, Missouri, hereby applies for an inspection warrant pursuant to 21 U.S.C. 374 for the purpose of inspecting the establishment identified as follows to determine the compliance of the owners and operators of Jamieson-McKames Pharmaceuticals, Inc., with the Federal Food, Drug and Cosmetic Act:

JAMIESON-McKAMES PHARMACEUTICALS, INC.

ALSO DOING BUSINESS AS PHARMACARE PHARMACY, INC.

3227 MORGANFORD ROAD

ST. LOUIS, MISSOURI

1. Information available to the Food and Drug Administration shows that Jamieson-McKames Pharmaceuticals, Inc. received magnesium salicylate tablets, a drug, from sources outside the State of Missouri. These tablets are of the shape and color of the brand name drug, Motrin, manufactured by the Upjohn Company.

2. Information availble to the Food and Drug Administration indicates that Jamieson-McKames repacks these magnesium salicylate tablets into bottles which are then labeled with the Motrin brand name.

3. Information supplied to the Food and Drug Administration indicates that Jamieson-McKames packages or manufactures other drugs which resemble other brand name drugs in shape and appearance and that Jamieson-McKames labels these look-alike drugs as brand name drugs. These drugs include but are not limited to Roche's Librium, Librax, Valium and Dalmane; Burroughs Wellcome Co. Zyloprim, Septra and Sudabid; and Pfizer's Urobiotic.

4. Information available to the Food and Drug Administration indicates that drugs, including the above named, are new drugs for which Food and Drug Administration approval would be required before they could be marketed. Review of new drug applications on file with the Food and Drug Administration revealed that neither Jamieson-McKames Pharmaceuticals, Inc. nor Pharmacare Pharmacy, Inc. has received approval for any new drug.

5. The inspection will be conducted within regular business hours. The investigators may be accompanied by one or more investigators duly authorized pursuant to 21 CFR 2.121(p). Written notice and the investigators' credentials will be presented as prescribed by 21 U.S.C. 374. The inspection will begin as soon as practicable after the issuance of this warrant and will be completed with reasonable promptness.

6. The inspection will extend to the establishment and all pertinent equipment, finished and unfinished materials, containers, labeling and all other things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs not in compliance have been processed, packed, transported, or held, or whether conditions exist which otherwise bear upon violation of the Act.

7. Samples will be collected when necessary to a reasonable inspection and receipt will be given therefor.

8. A return will be made to the Court at the completion of the inspection.

9. The authority for the issuance of the Inspection Warrant is 21 U.S.C. 374, *Camara* v. *Municipal Court,* 387 U.S. 523 (1967) and *See* v. *Seattle,* 387 U.S. 541 (1967) by the Supreme Court of the United States.

Sworn to before me, and subscribed in my presence, October 23, 1975.

/s/ STEVEN G. KENDALL
Food and Drug Investigator
United States Food and Drug
Administration

Before me /s/ William S. Bahn, United States Magistrate of the United States District Court for the Eastern District of Missouri, on the 23 day of October, 1975, Steven G. Kendall personally appeared, and upon oath stated that the facts set forth in this application are true to her knowledge and belief.

/s/ WILLIAM S. BAHN
United States Magistrate

APPENDIX H

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

IN THE MATTER OF ESTABLISHMENT INSPECTION
OF JAMIESON-McKAMES PHARMACEUTICALS, INC.,
ALSO DOING BUSINESS AS PHARMACARE
PHARMACY, INC., 3227 MORGANFORD ROAD,
ST. LOUIS, MISSOURI

Warrant for inspection under the Federal Food, Drug and Cosmetic Act

To Steven G. Kendall or any other authorized United States Food and Drug Investigator:

Application having been made, and probable cause shown, by Steven G. Kendall, United States Food and Drug Investigator, for an inspection of the establishment described as:

JAMIESON-McKAMES PHARMACEUTICALS, INC.

ALSO DOING BUSINESS AS PHARMACARE
PHARMACY, INC.

3227 MORGANFORD ROAD

ST. LOUIS, MISSOURI

Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374 and the decision of the Supreme Court in *Camara* v. *Municipal Court,* 387 U.S. 523 (1967) and *See* v. *Seattle,* 387 U.S. 541 (1967) you are authorized , accompanied by other Investigators and representatives of the United States Marshal, to enter the above-described premises at reasonable times during ordinary business hours and to inspect the above-described premises in a reasonable manner and to a reasonable extent.

Such inspection shall include an inspection of the establishment and all pertinent equipment, including but not limited to vehicles on the premises, finished and unfinished materials, containers, labeling and all records subject to inspection pursuant to Title 21, U.S.C., Section 374(a)(2).

A return shall be made to this Court showing that the inspection has been completed.

Dated: This 23 day of October, 1975.

/s/ WILLIAM S. BAHN
United States Magistrate

Return

Inspection of the establishment described in this warrant was made on 10/29/75, 10/30/75, 10/31/75, 11/3/75, and 11/5/75.

/s/ STEVEN G. KENDALL
Investigator, U.S. Food and
Drug Administration

On these dates, pursuant to the Complaint for Forfeiture, Cause No. 75-985-C(3), Eastern District of Missouri, and the Warrant for Arrest for Property issued by the Clerk of said court on October 29, 1975, and further pursuant to the Amended Complaint for Forfeiture and Amended Warrant for Arrest of Property filed and issued November 3, 1975, various items of drugs were seized from the premises of Jamieson-McKames Pharmaceuticals, Inc., also doing business as Pharmacare Pharmacy. A return on said Warrant and Amended Warrant has been filed with the Clerk of the District Court by Deputy U.S. Marshall Robert Winkelman. A copy of said return consisting of seventeen handwritten pages is attached hereto.

/s/ STEVEN G. KENDALL

/s/ WILLIAM S. BAHN

Sworn to and subscribed before me this 6 day of Nov. 1975.

APPENDIX I

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. District Address

1009 Cherry St.
Kansas City, Mo. 64106

2. Name and Title of Individual

James C. Jamieson, Sr.

3. Date 10-29-75

4. Firm Name

Jamieson-McKames Pharmaceuticals, Inc., also doing business as Pharmacare Payless Pharmacy

5. Hour 10:00 a.m.

6. Number and Street

3227 Morganford

7. City and State

St. Louis, Missouri

8. Zip Code 63116

Notice of Inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374

(a)][1] and/or Part F or G, Title III of the Public Health Service

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[1] Applicable portions of Section 704 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704. (a) For purposes of enforcement of this Act, officers of employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factor, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, inspection shall extend to all things therein (*including records, files, papers, processes, controls, and facilities*) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (*other than data as to qualifications of technical and professional personnel performing functions subject to this Act*), and (E) research data (*other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505 (j) of this Act*). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Act [42 USC 262-264].[2]

9. Signature (*Food and Drug Administration Employee(s)*)

Charles D. Bringman
Steven L. Kendall
James E. McDonald
Wilma O. Ele

10. Title (*Food and Drug Administration Employee(s)*)

Consumer Safety Officers

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[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 USC 262 - 264] are quoted below:

Part F - Licensing — Biological Products and Clinical Laboratories and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health, Education, and Welfare, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ***** Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (*or testing programs*) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of footnote 2 continued

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this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (*including testing records*), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer of employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

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(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less then $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer, to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall upon making such election, give prompt notice of such election (*together with information identifying the notifier and the product*) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of footnote 2 continued

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products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

Sec. 360 B.(a) It shall be unlawful—

(1) ***

(2) ***

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 360A;"

(4) ***

Part G — Quarantine and Inspection.

Sec. 361(a) "The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

APPENDIX J

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. District Address

1009 Cherry Street
Kansas City, Mo. 64106

2. Name and Title of Individual

Mr. Larry Lee Malof - Registered Pharmacist

3. Date 10-29-75

4. Firm Name

Pay-Less Pharmacy, Inc.

5. Hour 10:13 a.m.

6. Number and Street

514 W. Pearce

7. City and State

Wentzville, Missouri

8. Zip Code 63385

Notice of Inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.

374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 USC 262-264].[2]

9. Signature (*Food and Drug Administration Employee(s)*)

Richard D. Turner
Harold Willis

10. Title (*Food and Drug Administration Employee(s)*)

Investigator
Inspector

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[1] Footnotes 1 and 2 are the same as on Appendix I.

APPENDIX K

Constitution of United States

Amendment IV

Searches and seizures

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

APPENDIX L

§321. Definitions; generally

For the purposes of this chapter—

* * * *

(g)

* * * *

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor.

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

* * * *

(i)

* * * *

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

§ 333. Penalties—Violation of section 331 of this title

(a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

Second offenses; intent to defraud or mislead

(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

§ 334. Seizure—Grounds and Jurisdiction

(a) (1) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of seciton 344 or 355 of this title, be introduced into interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in the case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, and (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs.

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

Poisonous, insanitary, etc., Ingredients: adequate controls in manufacture

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) (A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 376(a) of this title, or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 376(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title.

Strength, quality, or purity differing from official compendium

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this subsection, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United StatesPharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

Misrepresentation of strength, etc., where drug is unrecognized in compendium

(c) If is is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

False or misleading label

(a) If its labeling is false or misleading in any particular.

* * * *

Health-endangering when used as prescribed

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

* * * *

Antibiotic drugs improperly certified

(l) If it is, or purports to be, or is represented as a drug (except a drug for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antiobiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug: *Provided,* That this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357(c) or (d) of this title.

§ 374. Inspection—Right of agents to enter; scope of inspection; notice; promptness; exclusions

(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provison of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this chapter), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (j) or section 357(d) or (g) of this title, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may be regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Written report to owner: copy to Secretary

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Receipt for samples taken

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Analysis of samples furnished owner

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

June 25, 1938, c. 675, § 704, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, c. 350, § 1, 67 Stat. 476; Oct. 10, 1962, Pub.L. 87-781, Title II, § 201(a), (b), 76 Stat. 792.

Opposition

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No. 81-950

In the Supreme Court of the United States

OCTOBER TERM, 1981

JAMIESON-MCKAMES PHARMACEUTICALS, INC.,
ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

REX E. LEE
Solicitor General

WILLIAM F. BAXTER
Assistant Attorney General

BARRY GROSSMAN
SUSAN J. ATKINSON
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

ARTHUR N. LEVINE
Deputy Chief Counsel
for Litigation

Office of General Counsel
Food and Drug Administration
Rockville, Md. 20857

QUESTIONS PRESENTED

1. Whether the Food and Drug Administration's possession of evidence of violations of the Federal Food, Drug, and Cosmetic Act that could be prosecuted criminally as well as civilly precludes it from obtaining an administrative warrant without satisfying the probable cause standards imposed on the issuance of warrants to investigate crimes.

2. Whether the lower courts correctly determined that petitioners' intentional and unauthorized use of the trademarks of other drug manufacturers for the purpose of representing petitioners' products to be those of the trademark owner constituted selling a "counterfeit drug" as defined in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(g)(2).*

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* In addition to Jamieson-McKames Pharmaceuticals, Inc., the petitioners are Pharmacare Generic Drugs, Inc., Pharmacare, Inc., Payless Pharmacy, Inc., James C. Jamieson, Sr., and James C. Jamieson, Jr.

TABLE OF CONTENTS

Page

Opinions below 1

Jurisdiction 2

Statement 2

Argument 7

Conclusion 19

TABLE OF AUTHORITIES

Cases:

Brotherhood of Locomotive Firemen & Enginemen v. *Bangor & Aroostook R.R.*, 389 U.S. 327 7
Camara v. *Municipal Court*, 387 U.S. 523 .... 9, 11, 13-14
Colonnade Catering Corp. v. *United States*, 397 U.S. 72 .... 8, 15
Delaware v. *Prouse*, 440 U.S. 648 13
Donovan v. *Dewey*, No. 80-901 (June 17, 1981) 8, 15, 16
G.M. Leasing Corp. v. *United States*, 429 U.S. 338 13
Graver Manufacturing Co. v. *Linde Co.*, 336 U.S. 271 18
Marshall v. *Barlow's, Inc.*, 436 U.S. 307 .... 9, 11, 12, 14
Marshall v. *Horn Seed Co.*, 647 F.2d 96 13
Michigan v. *Tyler*, 436 U.S. 499 .... 9, 10-11
Scott v. *United States*, 436 U.S. 128 12
See v. *Seattle*, 387 U.S. 541 14
Steagald v. *United States*, 451 U.S. 204 12
United States v. *Biswell*, 406 U.S. 311 .... 8, 14-15
United States v. *Consolidation Coal Co.*, 560 F.2d 214, vacated and remanded, 436 U.S. 942, prior judgment reinstated, 579 F.2d 1011, cert. denied, 439 U.S. 1069 12
United States v. *Device, Labeled Theramatic*, 641 F.2d 1289 13
United States v. *Dotterweich*, 320 U.S. 277 14
United States v. *Goldfine*, 538 F.2d 815 12
United States v. *Kordel*, 397 U.S. 1 .... 10, 12, 14

Cases—Continued **Page**

United States v. *Lawson*, 502 F. Supp. 158 13
United States v. *Pappas*, 613 F.2d 324 13
United States v. *Prendergast*, 585 F.2d 69 12
United States v. *Shaefer, Michael & Clairton Slag, Inc.*, 637 F.2d 200 13
Weinberger v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 15

Constitution, statutes and regulations:

United States Constitution, Fourth Amendment.... 8, 13
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* 7-8
  21 U.S.C. 331 15
  21 U.S.C. 331(f) 16
  21 U.S.C. 331(i)(3) 3
  21 U.S.C. 331(k) 3
  21 U.S.C. 331(p) 16
  21 U.S.C. 332 15
  21 U.S.C. 332(a) 16
  21 U.S.C. 333 16
  21 U.S.C. 333(b) 3, 17
  21 U.S.C. 334 3
  21 U.S.C. 334(a)(2)(C) 6
  21 U.S.C. 351 15
  21 U.S.C. 351(a) 15
  21 U.S.C. 351(b) 15
  21 U.S.C. 352(a) 15
  21 U.S.C. 352(k) 15
  21 U.S.C. 352(l) 15
  21 U.S.C. 352(m) 15
  21 U.S.C. 352(n) 15
  21 U.S.C. 355 15
  21 U.S.C. 360(b) 16
  21 U.S.C. 360(h) 16
  21 U.S.C. 374 16
  21 U.S.C. 374(a) 5, 8, 9, 11, 12, 14, 15, 16
  21 U.S.C. 374(a)(1)-(3) 16

18 U.S.C. 371 3
Mo. Ann. Stat. ch. 195 (Vernon 1972) 5
Mo. Ann. Stat. ch. 196 (Vernon 1972) 5
21 C.F.R. 211.1 *et seq.* 15

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A-1 to A-37) as amended on denial of rehearing (*id.* at A-38 to A-40) is reported at 651 F.2d 532.

The opinion of the district court in the criminal cases (Pet. App. A-53 to A-63) is not reported. The district court's order, memorandum, and findings of fact in the civil case (*id.* at A-64 to A-70) are reported at 475 F. Supp. 39. The order of the district court (Pet. App. A-41) affirming the report and recommendation of the magistrate (*id.* at A-42 to A-52) on petitioners' motion to suppress evidence is not reported.

JURISDICTION

The judgments of the court of appeals (Pet. App. A-71, A-37) were entered on May 21, 1981. Petitions for rehearing were denied and the government's motion for clarification granted (*id.* at A-38 to A-40) on August 7, 1981. The petition for a writ of certiorari was filed on November 18, 1981. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioners are four closely interrelated Missouri corporations and two of their chief executives.[1] The corporations manufactured, purchased, packaged, labeled, distributed, and sold drugs from before June 1972 until November 1975 (Pet. App. A-3 to A-4). Three of the corporate petitioners sold drugs directly to doctors, clinics, and pharmacies and two of the corporations operated a total of seven retail pharmacies (*id.* at A-3 to A-4).

Following a consolidated civil and criminal trial in the United States District Court for the Eastern

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[1] Petitioner Jamieson, Sr., was the president and treasurer of petitioner Jamieson-McKames Pharmaceuticals, Inc., and a member of its board of directors. He also was a member of the board of directors and vice-president and secretary of petitioner Pharmacare Generic Drugs and during 1975 he was a member of the board of directors of petitioner Pharmacare, Inc. (Pet. App. A-3).

Petitioner Jamieson, Jr., a board member, vice-president, and secretary of petitioner Jamieson-McKames Pharmaceuticals, Inc., was also a member of the board of directors, president, and treasurer of each of the other corporate petitioners (*ibid.*).

District of Missouri petitioners were found guilty on one count of conspiracy to violate the Federal Food, Drug, and Cosmetic Act, in violation of 18 U.S.C. 371, on ten counts of counterfeiting, misbranding and adulterating drugs, in violation of 21 U.S.C. 331 (i)(3) and 331(k), and with having committed these acts with intent to defraud and mislead, in violation of 21 U.S.C. 333(b) (Pet. App. A-53 to A-63). The two individual petitioners were each sentenced to eight years' imprisonment and fined $50,000;[2] each corporate petitioner was fined $22,000 ($2,000 on each of eleven counts) (Pet. App. A-2).

In the civil case, the district court found that petitioners had used certain equipment and machinery to produce counterfeit drugs (Pet. App. A-70). Accordingly, the court ordered that the equipment be condemned and forfeited to the United States pursuant to 21 U.S.C. 334 (Pet. App. A-70).

2. The evidence at trial demonstrated that petitioners had engaged in an extensive scheme of counterfeiting, misbranding and adulterating prescription drugs. These activities, which are described in detail in the court of appeals opinion (see Pet. App. A-20 to A-36) included:

a. Selling counterfeit and misbranded "Motrin." Petitioners sold tablets resembling those used by the Upjohn Company for the drug ibuprofen, which Upjohn sold under the trademark "Motrin." Petitioners sold their product in bottles labeled "Motrin" or "Motrin formula" although their tablets contained no ibuprofen and petitioners had no authorization from Upjohn to use its trademark (Counts II, III) (see Pet. App. A-20 to A-23).

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[2] The court suspended the sentences on Count IV and placed the individuals on probation for a period of five years following completion of the prison terms.

b. Selling counterfeit "Valium". "Valium" is a trademark held by Hoffman-LaRoche, Inc., for its patented drug diazepam. Petitioners sold tablets virtually identical in appearance to the Hoffman-LaRoche product, in bottles labeled "Valium" although the product was not manufactured by Hoffman-LaRoche and petitioners had no authorization to use the trademark or to manufacture the patented product (Count IV) (see Pet. App. A-23).

c. Adulterating and misbranding potassium phenoxymethyl penicillin (pen V). Petitioners purchased a shipment of pen V from Zenith Laboratories, a manufacturer, in January 1975, at a reduced price because of its August 1975 expiration date. Petitioners relabeled it potassium penicillin G (pen G) and extended the expiration date to July 1977 (Counts V, VI) (see Pet. App. A-23 to A-28).

d. Counterfeiting and misbranding the drug clindamycin hydrochloride. The patent for clindamycin is held by the Upjohn Company, which sells this drug under the trademark "Cleocin." Petitioners manufactured capsules which were labeled and bottled as "Cleocin", although they contained tetracycline rather than clindamycin.[3] Petitioners' drugs were not certified nor were they authorized by Upjohn (Counts VII, VIII) (see Pet. App. A-28 to A-30).

e. Adulterating and misbranding potassium penicillin G (pen G) pills. Petitioner purchased pen G pills from Mallinckrodt Chemical Works—at reduced prices—ground up the tablets and repackaged them in capsules labeled "Ampicillin." Ampicillin and pen G have different pharmacological effects, and can create a health risk when a patient for whom one is prescribed receives the other. Petitioners, moreover, failed to maintain appropriate documentation of their manufacturing activities and their drugs were not certified (Counts IX, X) (see Pet. App. A-30 to A-33).

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[3] Expert testimony indicated that this substitution could create major health risks and could be fatal to patients for whom clindamycin was prescribed (Pet. App. A-29 to A-30).

f. Misbranding Neomycin-Polymyxin eardrops. In September 1974, petitioners received a shipment of this drug with an expiration date of July 1975 and proceeded to relabel the drugs as expiring in August 1976 (Count XI) (see Pet. App. A-33 to A-34).

3. On four consecutive business days in October and November 1975, Food and Drug Administration (FDA) agents[4] inspected the premises of petitioners Jamieson-McKames Pharmaceuticals, Inc. (Jamieson-McKames) and Pharmacare, Inc. (Pharmacare), on Morganford Road in St. Louis (Pet. App. A-42). This was pursuant to a warrant for inspection issued by a United States magistrate (*id.* at A-75 to A-76). The inspectors also issued a notice of inspection pursuant to 21 U.S.C. 374(a) (Pet. App. A-77 to A-81). At the same time, the United States marshal seized drugs pursuant to a warrant for arrest of property issued by the clerk of the district court (*id.* at A-42). On October 29 and 30, 1975, FDA agents inspected petitioners' premises in Wentzville, Missouri (*id.* at A-43) and found the evidence which formed the basis for Counts VII and VIII. This search was conducted pursuant to a notice to inspect authorized by 21 U.S.C. 374(a) (Pet. App. A-82 to A-83). In Novem-

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[4] The FDA agents were accompanied by Missouri state inspectors acting pursuant to a Warrant for Inspection and Seizure under ch. 195, and a Warrant for Inspection under ch. 196, Mo. Ann. Stat. (Vernon 1972) (Pet. App. A-43). The state agents embargoed materials, but did not seize any items (*id.* at A-48). The government did not introduce any of these state-embargoed materials as evidence in the cases before the court (*ibid.*).

ber 1975, petitioners' former dispensary at the Chambers Medical Group in St. Louis was also inspected by an FDA agent (*id.* at A-19).

As a result of the inspection at the Morganford Road premises, in December 1975 the United States filed a civil complaint for forfeiture of certain items of equipment in Jamieson-McKames' possession. The complaint alleged that the equipment was used or designed for use in making counterfeit drugs and that it was therefore liable to seizure, condemnation and forfeiture pursuant to 21 U.S.C. 334(a)(2)(C) (C.R. 1-3; Pet. App. A-36).[5]

In May 1977, a grand jury in the Eastern District of Missouri indicted petitioners for the criminal violations at issue here (Pet. App. A-5).

In August 1977, the United States magistrate held a hearing on petitioners' motion to suppress certain evidence allegedly obtained illegally as the result of the searches at petitioners' business premises. The magistrate recommended that petitioners' motion be denied in all respects (Pet. App. A-42 to A-52) and the district court adopted that recommendation (*id.* at A-41).

The court of appeals found ample evidence to support the convictions on all counts and to support the condemnation in the civil action. Because the trial court had failed to resolve an issue of consent concerning the search at the Wentzville site,[6] however, the court of appeals vacated the convictions on Counts VII and VIII (relating to the Wentzville search), and remanded those counts for further proceedings. All other substantive findings in the case were affirmed (Pet. App. A-30, A-37).

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[5] The following abbreviations are used in this brief: "Cr.R." refers to the record filed in the criminal appeal (8th Cir. No. 79-1367); "C.R." refers to the record filed in the civil appeal (8th Cir. No. 79-1708); "Mag. Tr." refers to the transcript of proceedings before the United States magistrate at hearings on motions to suppress evidence in the criminal case; "Tr." refers to the transcript of proceedings in the consolidated trial before the district court.

ARGUMENT

The courts below correctly concluded that the evidence obtained in the FDA's inspection at petitioners' Morganford Road headquarters was properly admitted at trial, and that that evidence established, *inter alia*, that petitioners sold counterfeit drugs with intent to defraud and mislead purchasers in violation of the Federal Food, Drug, and Cosmetic Act. The decision below does not conflict with any decision of this Court or any other court of appeals and does not warrant review by this Court.

1. Counts VII and VIII, which the court of appeals remanded,[7] were the only ones where conviction was based on evidence obtained during a warrantless inspection. Consequently, contrary to petitioners' assertion (Pet. 13), resolution of this case does not require determining whether drug manufacturing is so pervasively regulated under the Federal Food,

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[6] The court concluded that the FDA notice to inspect would authorize a search unless consent were withheld, in which case a warrant would be required before the inspection could proceed (Pet. App. A-14).

[7] Because the court of appeals remanded as to those counts, its ruling with respect to the warrantless search is not yet ripe for review by this Court. *Brotherhood of Locomotive Firemen & Enginemen* v. *Bangor & Aroostook R.R.*, 389 U.S. 327 (1967). Moreover, petitioners state that their petition seeks review only of those counts on which the convictions were affirmed (Pet. 8).

Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, that no warrant is necessary to render an inspection of a drug manufacturer reasonable under the Fourth Amendment. *Donovan* v. *Dewey*, No. 80-901 (June 17, 1981); *United States* v. *Biswell*, 406 U.S. 311 (1972); *Colonnade Catering Corp.* v. *United States*, 397 U.S. 72 (1970).

The only inspection at issue here is the one conducted at petitioners' business premises on Morganford Road. Contrary to petitioners' assertion (Pet. 11), it has been clear throughout the course of these cases that the Morganford Road inspection was carried out pursuant to a Warrant for Inspection issued by a United States magistrate (Pet. App. A-75 to A-76). In addition, the FDA inspectors issued a notice of inspection pursuant to 21 U.S.C. 374(a) (*id.* at A-77 to A-81). Also, pursuant to a Warrant for Arrest of Property, the United States marshal seized drugs at that time (Attachment B to the government's brief in the Eighth Circuit).[8]

When the FDA inspectors arrived at the Morganford Road site at 10 A.M. on October 29, 1975, to begin the inspection, they presented the Warrant for Inspection, the notice of inspection and the inspectors' credentials to petitioner Jamieson, Sr. (Tr. 891-892, 1007; Mag. Tr. 18, 28; Pet. App. A-45).[9] Jamieson, Sr., examined the documents and told the inspectors to proceed with the inspection (*ibid.*).[10] These documents fully assured petitioners at the outset of the inspection that enforcement of the Federal Food, Drug, and Cosmetic Act required the inspection of their business premises, informed them of the lawful limits of the inspectors' power to inspect, and assured them that the inspectors present were acting under proper authorization. See *Camara* v. *Municipal Court*, 387 U.S. 523, 532 (1967); *Marshall* v. *Barlow's, Inc.*, 436 U.S. 307, 323 (1978). Moreover, the need and authority for the inspection had been reviewed and approved by a neutral magistrate.

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[8] The Warrant for Arrest of Property was issued pursuant to a complaint the government filed on October 29, 1975, for forfeiture of adulterated and misbranded drugs. A decree of condemnation was entered by default on December 12, 1975 (E.D. Mo. Civ. No. 75-985 C (3)).

[9] The deputy United States Marshal also presented the Warrant for Arrest of Property early in the inspection (Tr. 1140-1141).

Petitioners do not challenge the court of appeals' conclusion that the application established probable cause to issue a warrant to conduct an administrative inspection. They recognize (Pet. 15) that "'[p]robable cause in the criminal law sense is not required * * * to secure a warrant [for an] administrative search.'" Quoting *Marshall* v. *Barlow's, Inc.*, *supra*, 436 U.S. at 320; *Camara* v. *Municipal Court*, *supra*, 387 U.S. at 538. Relying on *Michigan* v. *Tyler*, 436 U.S. 499, 511-512 (1978), however, petitioners argue that such warrants may not issue in any case where

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[10] The inspection warrant specified the establishment to be inspected, the statutory and case law authority for the search, the fact that authorized FDA investigators and representatives of the United States Marshal were to carry out the inspection during ordinary business hours, and that the scope of the search was to be limited to that authorized by the inspection provision of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374(a) (Pet. App. A-75 to A-76). The notice of inspection issued in accordance with the requirements of 21 U.S.C. 374(a) included the entire text of the statutes which authorize the inspection (Pet. App. A-78 n.1, A-79 to A-81 n.2), and the names and titles of the FDA inspectors authorized to conduct the inspection (*id.* at A-79).

"the government contemplate[s] bringing criminal charges" (Pet. 16, quoting Pet. App. A-16 n.19), even where, as in this case, the immediate purpose for the inspection was the seizure of adulterated and misbranded drugs pursuant to a civil complaint for forfeiture (Tr. 1134-1135).[11]

While relying on *Michigan* v. *Tyler*, petitioners do not assert that the same factual pattern obtains here. That case involved a series of warrantless entries by fire officials, and this Court held that the initial entries were reasonable since they were related to the exigency of a burning fire and the need to discover its cause to prevent its recurrence. Once the fire was completely extinguished, however, subsequent entries could not be justified by any exigency and were deemed to be separate and independent entries for the purpose of investigating the cause of the blaze and were unreasonable absent an administrative warrant. 436 U.S. at 512. If in the course of such a subsequent investigation "the investigating officials find probable cause to believe that arson has occurred and require further access to gather evidence for a possible prosecution, they may obtain a warrant only upon a traditional showing of probable cause applicable to searches for evidence of crime" (*ibid.*). But, petitioners do not assert that midway in the course of the administrative inspection at Morganford the agency's thoughts turned to possible criminal prosecution.[12] Rather, they assert that because criminal prosecution was "contemplated" from the start, the agency—having some evidence of violation—could not rely on an administrative warrant.

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[11] At the time of the inspection of petitioners' Morganford Road premises, the only enforcement decision which had been made by the FDA was the decision to institute a civil seizure and forfeiture action against adulterated and misbranded drugs in petitioner Jamieson-McKames' possession. The agency had not yet decided whether to recommend criminal prosecution (Tr. 1137). As this Court has recognized, "[t]he public interest in protecting consumers throughout the Nation from misbranded drugs requires prompt action by the agency charged with responsibility for administration of the federal food and drug laws. But a rational decision whether to proceed criminally against those responsible for the misbranding may have to await consideration of a fuller record than that before the agency at the time of the civil seizure of the offending products." *United States* v. *Kordel*, 397 U.S. 1, 11 (1970).

Whether or not an inspector has reason to suspect that a criminal violation has occurred, an administrative warrant is adequate if one of the purposes of the inspection is to determine if there has been compliance with the standards of the Act. The regulatory character of the Morganford Road inspection was not diminished by the fact that it was predicated on evidence of existing violations. See *Marshall* v. *Barlow's, Inc., supra,* 436 U.S. at 320. The basic rationale for demanding a more compelling showing of probable cause where the purpose of the intrusion is to uncover the fruits or instrumentalities of crime is thus inapposite in this context. See *Camara* v. *Municipal Court, supra,* 387 U.S. at 535. Indeed, the scope of the inspection at Morganford was no broader than it would have been had the inspectors had no idea that criminal charges might result. Accordingly, the magistrate would have been correct in issuing the Warrant for Inspection even if the investigator had simply stated that inspection was necessary to carry out a general administrative plan to enforce the Act. *Marshall* v. *Barlow's, Inc., supra*, 436 U.S. at 321.

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[12] Although the inspection at Morganford Road took place over a four day period, the inspection was a continuous one requiring but a single warrant. Congress recognized that inspections may require more work than can be accomplished in a normal work day. Therefore, it provided that "[a] separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection." 21 U.S.C. 374(a).

To require a showing of criminal probable cause because evidence is found that could result in criminal prosecution, when a lesser showing would suffice for a routine statutory inspection, would frustrate enforcement of the Act and defeat attainment of its policy objectives. Cf. *United States* v. *Kordel*, 397 U.S. 1, 11 (1970). Where, as in the case of FDA inspections, an inspection is routinely permissible on an administrative basis (21 U.S.C. 374(a)), it would be anomalous indeed if the threshold probable cause requirement were raised and the authority to inspect narrowed when the government has some evidence that a drug manufacturer has violated the Act. Cf. *Scott* v. *United States*, 436 U.S. 128, 136-138 (1978). For this reason, the courts of appeals have uniformly held, as did the court of appeals below (Pet. App. A-18 & n.20), that so long as the extent of the inspection is limited in scope to that specified in the statute, no showing under traditional criminal standards of probable cause is necessary. *United States* v. *Prendergast*, 585 F.2d 69, 70-71, (3d Cir. 1978); *United States* v. *Consolidation Coal Co.*, 560 F.2d 214, 221 (6th Cir. 1977), vacated and remanded, 436 U.S. 942 (1978), prior judgment reinstated, 579 F.2d 1011 (1978), cert. denied, 439 U.S. 1069 (1979); *United States* v. *Goldfine*, 538 F.2d 815, 819 (9th Cir. 1976).[13]

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[13] Contrary to petitioners' assertion (Pet. 17), the decision of the court of appeals does not conflict with decisions of this Court or of any other court of appeals. In *Steagald* v. *United States*, 451 U.S. 204 (1981), this Court held that absent

This Court has stated that "[i]f a valid public interest justifies the intrusion contemplated, then there is probable cause to issue a suitably restricted search

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consent or exigent circumstances, a private home may not be entered to conduct a search or effect an arrest without a warrant. In *G.M. Leasing Corp.* v. *United States*, 429 U.S. 338 (1977), the Court held that warrantless searches of commercial property done for purposes of seeking contraband or evidence of crime violate the Fourth Amendment but that the Constitution does not require a warrant for the seizure of property from a public place. *Delaware* v. *Prouse*, 440 U.S. 648 (1979); *United States* v. *Shaefer, Michael & Clairton Slag, Inc.*, 637 F.2d 200 (3d Cir. 1980); and *United States* v. *Pappas*, 613 F.2d 324 (1st Cir. 1979), involved warrantless searches and seizures of automobiles. The Morganford Road inspection, however, was authorized by an inspection warrant and a Warrant for Arrest of Property issued by a United States magistrate and by an administrative notice of inspection. *United States* v. *Device, Labeled Theramatic*, 641 F.2d 1289 (9th Cir. 1981), involved the seizure of equipment from a physician's office pursuant to a warrant for seizure issued as a matter of routine by the clerk of a district court. Unlike the Morganford Road inspection, no inspection warrant was issued by a magistrate (*id.* at 1291). *Marshall* v. *Horn Seed Co.*, 647 F.2d 96 (10th Cir. 1981), concerns the showing of probable cause required to obtain an administrative warrant, which is not at issue in this case.

In *United States* v. *Lawson*, 502 F. Supp. 158, 164 (D. Md. 1980), administrative warrants were obtained more than two weeks after the government had made an institutional commitment to the defendants' criminal prosecution, and were used solely to gather evidence for that criminal prosecution. At the time of the Morganford Road inspection, the government had filed a civil complaint for forfeiture of various adulterated and misbranded drugs in petitioner Jamieson-McKames' possession. However, no institutional decision to request criminal prosecution had been made. See page 10, note 11, *supra*. Thus, unlike the situation in *Lawson*, the FDA's only commitment at the time of the Morganford Road inspection was to pursue civil remedies.

warrant." *Camara* v. *Municipal Court, supra,* 387 U.S. at 539. There is no gainsaying the public's legitimate interest in protecting itself against manufacturers or distributors of adulterated, misbranded or counterfeit drugs. *United States* v. *Kordel, supra,* 397 U.S. at 11; *United States* v. *Dotterweich,* 320 U.S. 277, 280-281 (1943). That public interest justifies routine inspection of drug manufacturing premises pursuant to an administrative warrant. *Marshall* v. *Barlow's, Inc., supra,* 436 U.S. at 320-321; *Camara* v. *Municipal Court, supra,* 387 U.S. at 538. And this justification is not diminished in any way when the agency has reason to believe that a violation may, in fact, have occurred. An inspection based on suspicion does not invade a drug manufacturer's legitimate expectation of privacy because it is no more intrusive than a routine inspection to which all such establishments are subject; both types of inspections are limited in scope to that authorized in 21 U.S.C. 374(a).

2. Although it was not critical to its holding with respect to the legality of an FDA inspection pursuant to an administrative warrant, the court of appeals (Pet. App. A-17 to A-18) properly concluded that because the drug manufacturing industry has a history of such close federal regulation, reasonable expectations of privacy in a manufacturer's business premises would not be violated by a warrantless administrative inspection, as long as he was on notice of the scope and legal authority on which the investigation is based.

In the absence of consent, a warrant ~~generally~~ is ordinarily required before a government official may enter commercial premises (*See* v. *Seattle,* 387 U.S. 541, 544 (1967)). Nevertheless, this Court has permitted warrantless inspections for "pervasively regulated business[es]" (*United States* v. *Biswell, supra,* 406 U.S. at 316; *Donovan* v. *Dewey*, *supra*, slip op. 11) "long subject to close supervision and inspection" (*Colonnade Catering Corp.* v. *United States*, *supra*, 397 U.S. at 77). The drug-manufacturing industry has such a long history of supervision and inspection. As the court of appeals recognized, "[i]t is difficult to overstate the urgent nature of the public health interests served by effective regulation of our nation's drug-manufacturing industry" (Pet. App. A-8 to A-9). Virtually every phase of the drug industry is heavily regulated;[14] prior FDA approval is required before new drugs can be marketed;[15] sanitary and quality control standards for production are specified; and extensive regulations are imposed with respect to every aspect of drug production, packaging, labeling and distribution. 21 C.F.R. 211.1 *et seq.* Moreover, a drug manufacturer knows that the FDA has the legal authority to inspect its premises, facilities, materials and records to determine compliance with all of the Act's requirements.[16] Every drug manufacturer must

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[14] See 21 U.S.C. 331 and 332 which deal, *inter alia*, with adulterated drugs and devices (21 U.S.C. 351 generally), adequate controls in manufacture (21 U.S.C. 351(a)), strength, quality, or purity (21 U.S.C. 351(b)), false or misleading labeling (21 U.S.C. 352(a)), certification of certain drugs (21 U.S.C. 352(k) and (l)), color additives (21 U.S.C. 352 (m)) and prescription drug advertising (21 U.S.C. 352(n)).

[15] 21 U.S.C. 355, outlines the requirements for new-drug applications, filing procedures, exemptions, records and reports. FDA regulations specifically prescribe the methods to be used to establish the safety and efficacy of a drug. See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 630-631 (1973).

[16] 21 U.S.C. 374(a) authorizes FDA inspectors to enter and inspect "any factory, warehouse, or establishment" in which drugs are "manufactured, processed, packed, or held for introduction into interstate commerce." It also authorizes FDA

register with the Secretary of Health and Human Services on or before December 31 of each year, 21 U.S.C. 360(b).[17] The FDA is required to inspect every registered drug facility at least once every two years. 21 U.S.C. 360(h). Thus, like those who sell firearms or liquor, or operate mines, one who manufactures or distributes drugs in interstate commerce does so with a reduced expectation of privacy from governmental inspection of its premises. In these circumstances, a warrant is not necessary if the purpose and limits of the inspection are reasonable. Since FDA could carry out a statutory inspection without a warrant, it certainly should be allowed to inspect

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inspectors to inspect all "equipment, finished and unfinished materials, containers, and labeling" pertinent to drug manufacturing, processing, packing, and storage for introduction into interstate commerce. The inspection authority extends to "all things * * * (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs" have been "manufactured, processed, packed, transported, or held" in violation of the Act. However, 21 U.S.C. 374 tailors the inspection authority to the health concerns of the Act (see *Donovan* v. *Dewey*, *supra*, slip op. 6) by barring inspection of "financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to [regulation under the Act]), and research data" other than data relating to drugs subject to regulation under the Act. It also limits the scope of inspections which may be conducted at retail pharmacies, research institutions, and the offices of medical practitioners. 21 U.S.C. 374(a)(1)-(3).

If the operator of an establishment subject to inspection under Section 704 refuses to allow a warrantless inspection, the Secretary is authorized to institute injunctive and/or criminal proceedings. 21 U.S.C. 331(f), 332(a) and 333.

[17] Failure to register is a crime (21 U.S.C. 331(p)).

pursuant to a warrant which indicates the authorization and scope of the intended search.

3. Contrary to petitioners' assertion (Pet. 20), the court of appeals did not hold "that the marketing of look-alike drugs is a sufficient basis for a criminal conviction and a civil forfeiture." Rather, the court of appeals held that "[t]he essence of counterfeiting is the unauthorized use of the trademark, trade name, or other identifying mark" of another manufacturer (Pet. App. A-21 n.26).[18] And, as indicated *supra*, pages 3-4, the court of appeals' rulings affirming petitioners' counterfeiting convictions and the civil forfeiture were based in each instance on evidence establishing that petitioners sold drugs in bottles bearing the unauthorized trademarks of other manufacturers, thereby falsely representing the drugs to be the products of the other manufacturers.[19] We agree with

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[18] The court of appeals recognized that even the evidence which established that many of petitioners' drugs contained none of the active ingredients of the drugs named on the bottle labels was irrelevant to the charge of counterfeiting (Pet. App. A-21 n.26). What this and the look-alike evidence confirmed, however, was that the mislabeling that rendered the drugs counterfeit was not inadvertent, but, rather, was done with intent to defraud and mislead. This additional finding of fraudulent and misleading intent was necessary to establish felony violations under 21 U.S.C. 333(b) (Pet. App. A-22, A-35 to A-36).

[19] Petitioners' contention that this case is similar to *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, Nos. 80-2182, 81-11 (argued Feb. 22, 1982), is frivolous. The manufacturers in *Ives* sold generic drugs in bottles properly marked with the name of the manufacturer; in no instance did they include on their packaging the trademark of the brand name manufacturer, nor did they sell a patented drug without authorization from the patentee; and there is no issue concerning the therapeutic equivalence of the generic and brand name drugs.

petitioners' assertion that "[t]he legislative history clearly indicates that the [Act's prohibition on counterfeit drugs] was never intended to apply to the manufacture of legitimate generic drugs" (Pet. 22). But, petitioners did not manufacture legitimate generic drugs. Contrary to petitioners' representation (Pet. 23), both courts below found overwhelming evidence that petitioners sold numerous drugs that fraudulently purported to be the drugs of other manufacturers. The courts found that petitioners packed their drugs in containers bearing false labels and the trademarks of other companies, not "to avoid confusion" (Pet. 23), provide "easy reference" (*ibid.*) and "ease of identification" (Pet. 24) for consumers, but with the clear intent to defraud and mislead and gain extremely high profits thereby (Pet. App. A-35 to A-36, A-56 to A-57, A-60). There is no need for this Court to reexamine such factual determinations. *Graver Manufacturing Co.* v. *Linde Co.*, 336 U.S. 271, 275 (1949).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

Rex E. Lee
Solicitor General

William F. Baxter
Assistant Attorney General

Barry Grossman
Susan J. Atkinson
Attorneys
Department of Justice

Arthur N. Levine
Deputy Chief Counsel
for Litigation
Office of General Counsel
Food and Drug Administration

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